Health Evidence Review Commission's

Value-based Benefits Subcommittee

March 14, 2013

Meridian Park Hospital
Community Health Education Center, Room 117B&C
19300 SW 65th Avenue, Tualatin, OR 97062

Section 1

Agenda

AGENDA
VALUE-BASED BENEFITS SUBCOMMITTEE
March 14, 2013
8:30am – 2:0pm
Meridian Park Hospital
Community Health Education Center, Room 117B&C
19300 SW 65th Avenue, Tualatin, OR 97062
A working lunch will be served at approximately 12:00 PM
All times are approximate

I. Call to Order, Roll Call, Approval of Minutes – Lisa Dodson 8:30 AM

II. Staff report –Ariel Smits, Cat Livingston, Darren Coffman 8:35 AM
A. Errata
B. Organizational chart of various committees

III. Follow Up Discussion Items – Ariel Smits 8:45 AM
A. Pseudobulbar affect --with Dr. Wayne Englander (via phone)

IV. **New Discussion Items – Ariel Smits 9:15 AM**
A. Uterine artery embolization--with Dr. Mary Costatino
B. Therapeutic activities—with Annette Broddie, OT (via phone)

V. Follow Up Discussion Items – HERC Staff 10:15 AM
A. Menstrual bleeding disorders
B. ICD-10 Urology guideline coding issue
C. ICD-10 Dermatology follow up issues

VI. Coverage Guidances for Prioritized List– HERC Staff 10:45 AM
EBGS
A. Chronic otitis media with effusion guideline
B. Management of recurrent acute otitis media in children
C. Cervical cancer screening
D. Coronary artery calcium scoring
E. Coronary computed tomography angiography

HTAS
F. Continuous blood glucose monitoring in diabetes mellitus
G. Diagnosis of sleep apnea in adults
H. Treatment of sleep apnea in adults
I. MRI for breast cancer diagnosis
J. Vertebroplasty, kyphoplasty, and sacroplasty

V. New Discussion Items – Ariel Smits/Cat Livingston 12:15 PM
A. Acupuncture for chronic pain conditions—with Ben Marx, MAcOM, LAc
1. Knee osteoarthritis
2. Chronic neck pain
3. Hip osteoarthritis
4. Shoulder pain/bursitis
5. General acupuncture guideline changes
C. Lung volume reduction surgery guideline
D. Bilateral cochlear implant guideline

E. Cervicobrachial syndrome
F. Chronic pelvic inflammatory conditions
G. Mental health codes on back pain lines

VI. Straight Forward Items – Ariel Smits **1:30 PM**

A. Straightforward table

VII. Biennial Review – Darren Coffman **1:45 PM**

IX. Public Comment **1:55 PM**

X. Adjournment – Lisa Dodson **2:00 PM**

Section 2

Minutes

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on (1/10/13)

For specific coding recommendations and guideline wording, please see the text of the1/10/13 VbBS minutes.

CODE MOVEMENT

■ Coronary brachytherapy procedure codes were limited to the four lines with coronary stenting codes.
■ Three diagnosis codes for exposure to various elements were moved to uncovered lines
■ Several diagnosis codes for personal history of various types of cancer were moved to covered lines
■ The HCPCPS code for electrostimulation of auricular acupuncture points was placed on the Excluded List. However, it is anticipated that the traditional electro acupuncture of the ear will continued to be covered with the existing CPT codes for acupuncture.
■ Stereotactic radiosurgery was added as a treatment option for arteriovenous malformations (AVMs).
■ Spinal enthesopathy was moved from a covered to an uncovered line
■ Spinal injection procedures were added to one line with spinal diagnoses

ITEMS CONSIDERED BUT NO CHANGES MADE

■ No changes were made to the current lack of coverage for enzyme replacement therapy for Gaucher's Disease
■ Coverage of silver compounds for treatment of dental caries was not added
■ No changes were made to the chronic otitis media guideline. This will be brought back to a future meeting for further discussion.

GUIDELINE CHANGES

■ A new guideline was adopted specifying that silver compounds are not covered for treatment of dental caries
■ A new guideline was adopted specifying that viscosupplemenation for osteoarthritis of the knee is not a procedure included on the Prioritized List
■ A new guideline was adopted specifying when epidural steroid injections are covered and specifying what procedures are not covered for treatment of low back pain
■ A new guideline was adopted referring immunization coverage to the Oregon Immunization Program
■ The Prevention Tables were modified to remove reference to immunizations
■ The radiculopathy guideline was modified to specify that reflexes must be "markedly" abnormal to qualify as radiculopathy
■ A new guideline putting therapies with high cost or low effectiveness on low priority lines was adopted

VALUE-BASED BENEFITS SUBCOMMITTEE
Meridian Park Health Education Center
January 10, 2013
9:00 AM – 1:00 PM

Members Present: Lisa Dodson, MD, Chair (departed at 11:55 AM); Kevin Olson, MD, Vice-chair (Chair Pro Tem from 11:55 AM – 1:05 PM); Chris Kirk, MD; James Tyack, DMD; David Pollack MD; Mark Gibson; Irene Croswell RPh; Laura Ocker, Lac; Susan Williams, MD.

Members Absent: none

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Jason Gingerich, Dorothy Allen

Also Attending: Denise Taray, DMAP; Jesse Little, OHA Actuarial Services Unit; Dan Manning, Sarah Iden, Ron Marchessauri, Lisa Valaika, Daniel Gruskin* and Dr. Pramad Mistry* (by teleconference), Genzyme; Dr. David Koeller, OHSU Pediatrics; Gary Allen, DMD, Advantage Dental; Deborah Loy, Capital Dental Care; Beryl Fletcher, Oregon Dental Association; Jason Parks, American Cancer Society Cancer Action Network; Jim Hoover, Bayer; Shannon Beatty, Medimmune; Mimi Luther, OHA Immunizations Program.

**Provided verbal testimony.*

Roll Call/Minutes Approval/Staff Report

The meeting was called to order at 9:00 am and roll was called. Minutes from the 12-13-12 VbBS meeting were reviewed and approved.

> ACTION: HERC staff will post the approved minutes on the website as soon as possible.

Coffman discussed moving the traditional December VbBS meeting to November to allow more time between the November and December meetings. For 2013, meetings will be scheduled for both November and December, with only one anticipated to be held, likely the November meeting. However, if the 2014 CPT codes are released later than expected, then the meeting will likely occur in December.

Straightforward Issues

- **Topic: Coronary brachytherapy**

  Discussion: Smits introduced a summary document limiting coverage of coronary brachytherapy to lines with coronary stenting codes. There was no discussion.

  Actions: Remove 92974 (coronary brachytherapy) from all current lines except:
  - **i. 51** CORONARY ARTERY ANOMALY
  - **ii. 76** ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION
  - **iii. 108** HEART FAILURE
  - **iv. 195** CHRONIC ISCHEMIC HEART DISEASE

New Discussion Items

- **Topic: External elements exposure issues**

  Discussion: Livingston introduced a summary document with proposed changes in placement of diagnosis codes for exposure to various elements. There was no discussion.

  Actions:
  1) Move 992.9 (Unspecified effects of heat and light) to line 688 DERMATOLOGICAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
  2) Move 994.5 (Exhaustion due to excessive exertion) to line 691 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
  3) Move 994.6 (motion sickness) to line 539 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM
  4) For the ICD-10 Prioritized List:
     a. Place T67.9xxA (Effect of heat and light, unspecified, initial encounter) on line 665
     b. Place T73.3xxA (Exhaustion due to excessive exertion, initial encounter) on line 668
     c. Place T 75.3xxA (Motion sickness, initial encounter) on line 518

- **Topic: Stereotactic radiation therapy for intracranial AVMs**

  Discussion: Smits introduced a summary document with recommendations to add stereotactic radiation therapy as a treatment for ateriovenous malformations (AVMs). There was discussion about whether there should be a guideline or

other criteria to determine when an AVM should be treated at all. There is some morbidity associated with treatment. However, these lesions are generally seen as requiring treatment to prevent a catastrophic or fatal bleed in the brain. Gibson brought up that there is a trial currently underway comparing conservative treatment of AVM vs. interventions. Olson found the trial and noted that it may still be recruiting patients, and that there is no known date when the trial results are expected to be published. The decision was to have no such guideline, but allow the individual patient and provider to decide when to treat.

There was discussion about the relative cost of stereotactic radiation vs. other therapies such as embolization. Actual costs are not known precisely; however, radiation treatment is outpatient, which lowers its overall cost. There was discussion about creating a guideline to define when radiation therapy should be done vs. other options; however, it was felt that this might be beyond the current evidence.

Dodson noted that some treatments for AVMs are already on the Prioritized List and may need to be re-examined for efficacy. The group felt that this type of review may need to be conducted by HTAS. After debate, the group felt that other therapies did not need to be reviewed at this time, but may be reviewed once the results of the RCT (the ARUBA trial) are known.

The final decision was to add stereotactic radiation therapy to the line with AVM diagnoses. HERC staff was asked to monitor for trial results and bring this topic back as needed.

Actions:

1) Add intracranial stereotactic radiosurgery (CPT 77263-77295, 77300, 77332-77336, 77370-77372, 77402-77416, 77432) to line 201 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN

- **Topic: Personal history of cancer V codes**

Discussion: Smits introduced a document proposing placement of various personal history of cancer diagnosis codes on funded lines. There was minimal discussion.

Actions:

1) V10.09 (Personal history of malignant neoplasm of other gastrointestinal tract) was moved to lines 165 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS, 277 CANCER OF RETROPERITONEUM, PERITONEUM, OMENTUM AND MESENTERY, 341 CANCER OF PANCREAS, 459 CANCER OF GALLBLADDER

2) V10.29 (Personal history of malignant neoplasm of other respiratory and intrathoracic organs) was moved to lines 207 CANCER OF SOFT TISSUE , 276 CANCER OF ENDOCRINE SYSTEM, EXCLUDING THYROID; CARCINOID SYNDROME, 278 CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS
3) V10.44 (Personal history of malignant neoplasm of other female genital organs) was moved to line 311 CANCER OF VAGINA, VULVA AND OTHER FEMALE GENITAL ORGANS
4) V10.69 (Personal history of other leukemia) was moved to lines 181 ACUTE NON-LYMPHOCYTIC LEUKEMIAS, 310 CHRONIC LEUKEMIAS; POLYCYTHEMIA RUBRA VERA
5) V10.79 (Personal history of other lymphatic and hematopoietic neoplasms) was moved to lines 221 NON-HODGKIN'S LYMPHOMAS, 249 ACUTE LYMPHOCYTIC LEUKEMIAS (ADULT) AND MULTIPLE MYELOMA, 310 CHRONIC LEUKEMIAS; POLYCYTHEMIA RUBRA VERA
6) V10.88 (Personal history of malignant neoplasm of other endocrine glands and related structures) was moved to line 207 CANCER OF SOFT TISSUE
7) V10.91 (Personal history of malignant neuroendocrine tumor) was moved to lines 209 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA, 276 CANCER OF ENDOCRINE SYSTEM, EXCLUDING THYROID; CARCINOID SYNDROME, 622 SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS

Previous Discussion Items

- **Topic: Other December follow up - Auricular acupuncture**

Discussion: Smits introduced a document with several possible placements for the HCPCS code for electrical stimulation of auricular acupuncture points. Testimony from several experts was introduced. Smits and Ocker both discussed that there appears to be confusion in the acupuncture community about the use of this code. The subcommittee felt that this code could be placed on the Excluded List, and if this causes problems with billing, then acupuncture providers can request that this code be re-reviewed. It is anticipated that acupuncturists can continue to use the current acupuncture CPT codes for in-office electrical stimulation of auricular points. The group did not feel that there was a need for a specific guideline prohibiting coverage of the proprietary ambulatory devices which stimulate these sites at this time.

Actions:

1) Recommend placing S8930 Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient on the Excluded List

- **Topic: Enzyme replacement therapy - Gaucher's disease**

  Discussion: Livingston introduced a document summarizing the current evidence for enzyme replacement therapy (ERT) for Gaucher's disease. Daniel Gruskin, from Medical Affairs at Genzyme, provided testimony that before ERT, individuals did not grow and gain weight. He provided comments on costs, and estimated that for a 65kg patient, the cost with perfect compliance would be approximately $250,000 a year. This price has been stable and not expected to go down in the future. There were questions about why it is so expensive, with the answer being that because it is a biologic product and it is a rare disease, the enzyme replacement therapy is very expensive to produce.

  Dr. Pramod Mistry gave testimony on behalf of Genzyme. Dr. Mistry is the founding director of the NHS Gaucher disease treatment center. Dr. Mistry provided the following disclosures—he has received research grants from Genzyme Sanofi, funded by NIH, and the National Gaucher Foundation (patient advocacy organization). He presented some clinical background and pointed out that the pattern of progression of the disease varies at different ages as well as there being a heterogeneous phenotypic presentation making it hard to predict natural history in any one individual, although disease is progressive. He presented two individual cases. The registry is a partnership between academia and industry and patient advocacy organizations. Splenectomies have decreased since 1990. He indicated that there will be a Cochrane review published in a few months. There is a new drug which is a substrate reduction therapy which will be tested in a placebo controlled trial with 60 patients in 12 countries and is also expected to be published in the near future.

  Dr. Koeller, OHSU, pediatric metabolic physician at OHSU. Director of OHSU Metabolic Clinic, gave testimony. He disclosed that he had no conflicts of interest. He argues that ERT for Gaucher's disease should be covered. This is a rare condition, there are no RCTs, and there is variability between patients. He indicated that there was interest in better understanding of the natural history of untreated disease.

  Questions were asked about the natural course of treatment. This is a lifelong treatment, the enzyme half life is only a few days, so enzyme needs to be continually replenished. Standard of care is to reduce the dose in a stepwise manner to use minimally effective dose. Longer term treatment is much less than the starting dose. Maintenance therapy is once a month. Treatment has to be individualized due to heterogeneity of phenotypes. The treatment generally requires 15-30 units/kg monthly.

  A question was asked about miglustat, a substrate reduction therapy. It is considered a second line agent for those that can't tolerate enzyme replacement. Therapeutic gains are significantly less than ERT, and given the side effects profile, this treatment is not considered first line. New study by Cox in Journal of

Orphan Disease looking at long-term maintenance therapy with enzyme shows nearly half of patients on miglustat discontinued therapy due to side effects. It is non-inferior, but could be maintenance therapy for a small subset of patients.

Subcommittee members discussed the challenges of a rare disease with heterogeneity and the types of evidence available. There is compelling information about the before and after data. A proposal was made to add coverage with a prior authorization process.

Questions were asked about the prevalence of Gaucher's disease in Oregon. There is one pediatric Gaucher patient in the current OHP/Medicaid population. At the OHSU metabolic disease clinic there are a total of 10-15 children with this disease. The symptoms can be debilitating and would disable people enough to not be gainfully employed. There are 15 patients in the US that receive completely free Cerezyme.

The final decision was to revisit this topic once the Cochrane review and the other placebo-controlled trial are available. No change was recommended to current coverage. If the Cochrane review is going to be delayed for an extended period, the VBBS will consider this topic again earlier. HERC staff will plan on placing this topic on the May VBBS agenda pending those studies.

Actions:

1) No changes were made to the current prioritization for enzyme replacement therapy for Gaucher's disease

- **Topic: Silver compounds for caries treatment**

Discussion: Livingston introduced a document with information regarding silver compounds for dental caries. Tyack shared that restoration of decayed teeth is the standard of care. He stated that he is opposed to having this replace standard of care. If evidence improves regarding the benefits of this type of therapy, then the VbBS could authorize utilization in a limited way with a strict guideline. Tyack sees the utility of this treatment primarily in third world environments. There may be limited situations in which this is a very good option (with additional data) including: medically compromised patients needing stabilization prior to dental care (people with recent MI), children waiting for hospital dentistry and don't want worsening of caries prior to restoration, and possibly primary posterior teeth close to exfoliation. Given that the vast majority of the costs of dental care are visit related, there are concerns about the costs of this given the need for frequent applications. It only makes sense if not going to do restoration, which is not standard of care. There are concerns that this type of treatment could delay definitive treatment.

Dr. Gary Allen testified. He wished to clarify that the American Academy of Pediatric Dentistry guideline allows for deferred care, one type of which is silver compound treatment. Dr. Allen testified against adding a guideline to state that this is not covered if the CPT code is placed on the Excluded List. Coffman noted that there is no specific code for silver compound treatment and therefore it cannot be added to the Excluded List.

Actions:

1) Coverage of silver compounds for treatment of dental caries was not adopted
2) A new guideline was adopted as shown in Appendix A specifying that silver compounds are not included on the Prioritized List for treatment of dental caries

Coverage Guidances

- **Topic: Viscosupplementation for osteoarthritis of the knee**

Discussion: Smits introduced a summary of changes recommended to bring the Prioritized List into agreement with the HERC Coverage Guidance on viscosupplementation for osteoarthritis of the knee. It was clarified that the CPT code is utilitized for a variety of procedures done on multiple joints and therefore could not be excluded. A guideline will be needed to exclude this particular procedure.

Actions:

1. A new guideline was added to lines 384, 455, and 489 as shown in Appendix A.

- **Topic: Percutaneous interventions for low back pain**

Discussion: Smits introduced a summary of changes recommended to bring the Prioritized List into agreement with the HERC Coverage Guidance on percutaneous interventions for low back pain. Kirk advocated that the new guideline contain a very specific definition for radiculopathy, as these procedures are commonly requested and need specific criteria. The group felt that the definition of radiculopathy found in Guideline Note 37 would be sufficient. The group felt that the actual wording of this guideline should be incorporated into the new guideline to make it easier for readers to find the criteria and for administrative law judges to rule on the intent of the Commission. Note: Guideline Note 37 was modified at this meeting and the new wording will be reflected in the new guideline. The decision was made to follow the recommendations in the summary, with the guideline modified as shown in Appendix A.

Actions:

1) Move 720.1 (Spinal enthesopathy) [M46.0 in ICD-10] from line 52 RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES to lines 516 PERIPHERAL ENTHESOPATHIES --MEDICAL THERAPY and 531 PERIPHERAL ENTHESOPATHIES--SURGICAL THERAPY
2) Add lumbar epidural steroid injections (CPT 62311, 64483, 64484) to line 400 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT
3) Add a new guideline regarding coverage of percutaneous interventions for low back pain to lines with low back pain diagnoses as shown in Appendix A

- **Topic: Management of chronic otitis media in children**

Discussion: Livingston introduced a summary of changes recommended to bring the Prioritized List into agreement with the HERC Coverage Guidance on management of chronic otitis media in children. There was discussion about when the co-morbidity rule should be applied for ear tubes. The group consensus was that the mentioned high risk groups (children with Down's syndrome, craniofacial anomalies, or cleft palate or children with documented speech and language delay with hearing loss and chronic otitis media) should have tubes covered. There was discussion about putting ear tube procedure codes on lines to pair with these diagnoses, but it was noted that providers would not pair the high risk condition, but rather chronic otitis media in these cases. The decision was that these high risk groups should have coverage explicitly called out in the guideline rather than using the co-morbidity rule. Various wording options were debated.

Actions:

1) HERC staff to work with Drs. Kirk and Shaffer to refine guideline wording and bring back to a future meeting as a straightforward issue.

Guidelines

- **Topic: Immunization table/Prevention tables**

Discussion: Smits introduced a summary document recommending striking references to immunizations from the Prevention Tables and adopting a new guideline stating that immunizations are covered as recommended by the Oregon Immunization Program (OIP). The committee wanted to specifically call out that the coverage is as recommended by the OIP, and this wording was added to the proposed guideline. There were questions about how the link would be updated, and staff responded that it would be checked with each new publication of a List. There was a question about why the Prioritized List simply did not refer to ACIP guidelines. Staff responded that there may be occasions when Oregon decides not to follow ACIP recommendations for a particular

vaccine or population group. Referring to OIP recommendations would allow statewide agreement on coverage.

Actions:
1) A new guideline regarding immunization coverage was adopted as shown in Appendix A
2) The Prevention Tables were modified as shown in Appendix C

- **Topic: Expensive/marginally effective drug guideline**

Discussion: Livingston introduced a document outlining a proposed new guideline to not cover minimally effective or very expensive therapies, as determined by the Pharmacy and Therapeutics (P&T) Committee. The committee asked for greater clarification about how the various HERC subcommittees and other committees at other state agencies work together. Staff gave a summary of the various committees involved and their responsibilities and location.

Staff discussed that by statute, the HERC cannot do evidence-based reviews of specific individual drugs, although the Commission can do reviews of treatments that include drugs and classes of drugs. The HERC does have the authority to prioritize drugs, but historically the Commission has decided not to do this, based partially on the lack of ability to link NDC codes with diagnosis on prescriptions. Prescription drugs have been treated as an ancillary service. The P&T Committee is undergoing work to create a list of expensive/marginally effective drugs already.

Questions were asked about whether a predefined definition for “marginal or clinically unimportant benefit” should be added to the proposed guideline. However, HERC staff felt that each therapy under consideration would need to be considered individually, in terms of the population affected, cost, alternate treatments available, and other factors. There was strong support for enabling the P&T Committee and HERC to conceptually work together.

Pollack suggested changing the title of the proposed guideline to read “marginal benefit or high cost” rather than “and/or” to specify that the intent is to limit both marginally effective drugs and drugs that may or may not be effective but have very high cost. Similarly, it was suggested to strike the “and” after clause 2 to reflect that any of the clauses would be sufficient for low prioritization.

The committee requested that staff bring back an organizational diagram of various state committees and commissions for greater member understanding.

Actions:
1) Adopt a new guideline as shown in Appendix A

a. Note: see the HERC minutes for January 10, 2013 for final accepted wording
b. Note: this guideline will not go into effect until October 1, 2013

2) Rename Line 692, "Gastrointestinal Conditions and Other Miscellaneous Conditions with No or Minimally Effective Treatments or No Treatment Necessary."
3) Staff to add to the next biennial review consideration list:
   a. Consider adding a new line to January 2016 list that separates out miscellaneous conditions from Line 692.
4) Staff to create and share with the commission an organizational diagram as requested.

- **Topic: Guideline Note 37 abnormal reflexes radiculopathy**

  Discussion: Livingston introduced a summary document with proposed modifications to the radiculopathy guideline. The group agreed to make the abnormal reflex clause stronger, and added the word "markedly" to this criteria rather than the proposed wording change.

  Actions:
  1) Guideline note 37 was modified as shown in Appendix B

- **Public Comment:**
  No additional public comment was received

- **Issues for next meeting:**
  - Guideline note 44 Menstrual Bleeding Disorders
  - Prioritization of pseudobulbar affect
  - Acupuncture for chronic pain diagnoses
  - Uterine artery embolization
  - Bilateral cochlear implants guideline
  - Changes to the Prioritized List required for agreement with HERC coverage guidances on management of recurrent acute otitis media in children, cervical cancer screening, treatment of attention deficit hyperactivity disorder, coronary artery calcium scoring, coronary computed tomography angiography, neuroimaging in headache, and femoracetabular impingement syndrome surgery
  - Modifications to the chronic otitis media treatment guideline

- **Next meeting/Adjournment**
  March 14, 2013, 9:00 am – 1:00 pm, Meridian Park Hospital, Room 117.

  The meeting was adjourned at 1:05 PM.

Apendix A
New Guidelines

New Guidelines Effective April 1, 2013

GUILDELINE 104, VISCOSUPPLEMENTATION OF THE KNEE

Lines 384, 455, 489

Viscosupplementation of the knee (CPT 20610) is not covered for treatment of osteoarthritis of the knee

GUIDELINE NOTE 105, EPIDURAL STEROID INJECTIONS, OTHER PERCUTANEOUS INTERVENTIONS FOR LOW BACK PAIN

Lines 52, 400, 434, 562, 607, 638

Epidural steroid injections (CPT 62311, 64483, 64484) are covered for patients with persistent radiculopathy due to herniated disc, where radiculopathy is as defined in Guideline Note 37 as showing evidence of one or more of the following:

A) Markedly abnormal reflexes
B) Segmental muscle weakness
C) Segmental sensory loss
D) EMG or NCV evidence of nerve root impingement
E) Cauda equina syndrome
F) Neurogenic bowel or bladder
G) Long tract abnormalities

It is recommended that shared decision-making regarding epidural steroid injection include a specific discussion about inconsistent evidence showing moderate short-term benefits, and lack of long-term benefits. If an epidural steroid injection does not offer benefit, repeated injections should not be covered. Epidural steroid injections are not covered for spinal stenosis or for patients with low back pain without radiculopathy.

The following interventions are not covered for low back pain, with or without radiculopathy:

- facet joint corticosteroid injection
- prolotherapy
- intradiscal corticosteroid injection
- local injections
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- radiofrequency denervation
- sacroiliac joint steroid injection
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- radiofrequency denervation

Appendix A
New Guidelines

GUIDELINE NOTE 106 IMMUNIZATIONS
Lines 3,4
Immunizations are covered as recommended by the Oregon Immunization Program. The current recommendations are found at this link: http://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/DMAPvactable.pdf

GUIDELINE NOTE 91, SILVER COMPOUNDS FOR DENTAL CARIES
Lines 58, 372, 373, 494, 621
Silver compounds for dental caries prevention and treatment are not included on these or any lines on the Prioritized List for coverage consideration.

New Guideline Effective October 1, 2013

Note: the wording of this guideline was changed at the 1/10/13 HERC meeting. Please see the HERC 1/10/13 minutes for final accepted wording

ANCILLARY GUIDELINE XXX, THERAPIES WITH MARGINAL BENEFIT OR HIGH COST

It is the intent of the Commission that therapies that exhibit one or more of the following characteristics generally not be included in the funded region of the Prioritized List:

i. Marginal or clinically unimportant benefit,
ii. Very high cost in which the cost does not justify the benefit
iii. Significantly greater cost compared to alternate therapies when both have similar benefit

Where possible, the Commission prioritizes pairings of condition and treatment codes to reflect this lower priority, or simply does not pair a procedure code with one or more conditions if it exhibits one of these characteristics.

As codes for prescription drugs and certain other ancillary services are not included on the Prioritized List, it is more difficult to indicate the importance of these services through the prioritization process. The Commission recognizes the evidence-based reviews being conducted by the Pharmacy and Therapeutics Committee and hereby prioritizes those services found in Table XX located at [website link to be determined] to be prioritized on the line listed below that corresponds with the condition being treated:

Appendix A
New Guidelines

ICD-9-CM Codes	Condition classification	Line
001-139, 771, V01-V09, V12.0, V18.8	Infectious & parasitic diseases	683
140-209, V10, V16, V58.0-V58.1, V67.1-V67.2	Malignant neoplasms	622
210-239	Benign neoplasms	656
240-279, 775, V12.1-V12.2, V18.0-V18.1	Endocrine, nutritional and metabolic diseases & immunity disorders	684
280-289, V12.3, V18.2-V18.3, V58.2	Diseases of the blood and blood-forming organs	685
290-319, V11, V17.0, V18.4, V67.3	Mental, behavioral and neurodevelopmental disorders	681
320-359, 740-742, 779, V12.4, V17.2, V58.72	Diseases of the nervous system	687
360-389, 743-744, V19.0-V19.3, V57.4, V58.71	Diseases of the sensory organs	686
390-459, 745-747, 773-774, 776, V12.5, V17.1, V17.3-V17.4, V58.73	Diseases of the circulatory system	685
460-519, 748, 769-770, V12.6, V17.5-V17.6, V57.0, V58.74	Diseases of the respiratory system	689
520-579, 749-751, 777, V12.7, V18.5, V58.75	Diseases of the digestive system	692
580-629, 752-753, V13.0, V13.2, V18.6-V18.7, V25-V26, V56, V58.76	Diseases of the genitourinary system	690
630-679, V13.1, V22-V24, V27-V28	Complications of pregnancy, childbirth and the puerperium	690
680-709, 757, 778, V13.3, V19.4, V58.77	Diseases of the skin and subcutaneous tissue	688
710-739, 754-756, V13.4-V13.5, V17.7-V17.8, V54, V57.1-V57.2, V57.8, V58.78, V67.4	Diseases of the musculoskeletal system and connective tissue	691
758-766, 768, 780-799, V13.6-V13.9, V14-V15, V18.9, V19.6-V19.8, V20-V21, V29-V39, V40-V53, V55, V57.3, V57.9, V58.3-V58.6, V58.8-V58.9, V59-V66, V67.0, V67.5-V67.9, V68-V91	Symptoms, signs and ill-defined conditions	692*
767-768, 772, 800-999	Injury and poisoning	663

Appendix B
Modified Guidelines

GUIDELINE NOTE 37, DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT

Line: 400

Neurologic impairment or radiculopathy is defined as objective evidence of one or more of the following:

A) Markedly abnormal reflexes
B) Segmental muscle weakness
C) Segmental sensory loss
D) EMG or NCV evidence of nerve root impingement
E) Cauda equina syndrome~~,~~
F) Neurogenic bowel or bladder
G) Long tract abnormalities

Otherwise, disorders of spine not meeting these criteria (e.g. pain alone) fall on Line 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT

Appendix C
Prevention Tables

Birth to 10 Years

Interventions Considered and Recommended for the Periodic Health Examination

Leading Causes of Death
Conditions originating in perinatal period
Congenital anomalies
Sudden infant death syndrome (SIDS)
Unintentional injuries (non-motor vehicle)
Motor vehicle injuries

Interventions for the General Population

SCREENING

Height and weight
Blood pressure
Vision screen (3-4 yr)
Hemoglobinopathy screen (birth)[1]
Phenylalanine level (birth)[2]
T4 and/or TSH (birth)[3]
Effects of STDs
FAS, FAE, drug affected infants[4]
Hearing, developmental, behavioral and/or psychosocial screens[5]
Learning and attention disorders[6]
Signs of child abuse, neglect, family violence

COUNSELING

Injury Prevention

Child safety car seats (age <5 yr)
Lap-shoulder belts (age >5 yr)
Bicycle helmet; avoid bicycling near traffic
Smoke detector, flame retardant sleepwear
Hot water heater temperature <120-130F
Window/stair guards, pool fence, walkers
Safe storage of drugs, toxic substances, firearms and matches
Syrup of ipecac, poison control phone number
CPR training for parents/caretakers
Infant sleeping position

Diet and Exercise

Breast-feeding, iron-enriched formula and foods (infants and toddlers)
Limit fat and cholesterol; maintain caloric balance; emphasize grains, fruits, vegetables (age >2 yr)
Regular physical activity*

Substance User

Effects of passive smoking*
Anti-tobacco message*

Dental Health

Regular visits to dental care provider*
Floss, brush with fluoride toothpaste daily*
Advice about baby bottle tooth decay*

Mental Health/Chemical Dependency

Parent education regarding:
- Child development
- Attachment/bonding
- Behavior management
- Effects of excess TV watching
- Special needs of child and family due to:
  - Familial stress or disruption
  - Health problems
  - Temperamental incongruence with parent
  - Environmental stressors such as community violence or disaster, immigration, minority status, homelessness
- Referral for MHCD and other family support services as indicated

[1]Whether screening should be universal or targeted to high-risk groups will depend on the proportion of high-risk individuals in the screening area, and other considerations . [2]If done during first 24 hr of life, repeat by age 2 wk. [3]Optimally between day 2 and 6, but in all cases before newborn nursery discharge. [4]Parents with alcohol and/or drug use. Children with history of intrauterine addiction. Physical and behavioral indicators: hypertension, gastritis, esophagitis, hematological disorders, poor nutritional status, cardiac arrhythmias, neurological disorders, intrauterine growth retardation, mood swings, difficulty concentrating, inappropriateness, irritability or agitation, depression, bizarre behavior, abuse and neglect, behavior problems. [5]Screening must be conducted with a standardized, valid, and reliable tool. Recommended developmental, behavioral and/or psychosocial screening tools include and are not limited to: a) Ages and Stages Questionnaire (ASQ); b) Parent Evaluation of Developmental Status, (PEDS) plus/minus PEDS:Developmental Milestones (PEDS:DM); c) ASQ:Social Emotional (ASQ:SE); and d) Modified Checklist for Autism in Toddlers (M-CHAT). [6]Consider screening with full DSM-IV criteria for attention deficit disorder, inattentive or hyperactive types, in children with significant overall academic or behavioral difficulty including academic failure and/or learning difficulty, especially in reading, math or handwriting.

Appendix C
Prevention Tables

*The ability of clinical counseling to influence this behavior is unproven.

Birth to 10 Years (Cont'd)

Interventions for the General Population (Cont'd)

~~**IMMUNIZATIONS**~~
~~Diphtheria-tetanus-acellular pertussis (DTaP)~~
~~Inactivated poliovirus (OPV)~~
~~Measles-mumps-rubella (MMR)~~
~~H. influenzae type b (Hib) conjugate~~
~~Hepatitis B~~
~~Varicella~~
~~Pneumococcal~~
~~Hepatitis A~~
~~Influenza~~
~~Rotavirus~~
~~Human papillomavirus (HPV)1.~~

CHEMOPROPHYLAXIS
Ocular prophylaxis (birth)

~~1HPV2 and HPV4 for females aged 9 to 26. HPV4 for males aged 9 through 26.~~

Interventions for the High-Risk Population

Hemoglobin/hematocrit (HR1)
HIV testing (HR2)
PPD (HR3)
~~Hepatitis A vaccine (HR4));~~
~~Pneumococcal polysaccharide vaccine (HR5)~~
~~Meningococcal vaccine (HR6)~~
Blood lead level (HR~~7~~4)
Daily fluoride supplement (HR~~8~~5)
Avoid excess/midday sun, use protective clothing* (HR~~9~~6)
Screen for child abuse, neurological, mental health conditions
Increased well-child visits (HR~~10~~7)

High-Risk Groups

HR1 = Infants age 6-12 mo who are: living in poverty, black, Native American or Alaska Native, immigrants from developing countries, preterm and low-birthweight infants, infants whose principal dietary intake is unfortified cow's milk.

HR2 = Infants born to high-risk mothers whose HIV status is unknown. Women at high risk include: past or present injection drug use; persons who exchange sex for money or drugs, and their sex partners; injection drug-using, bisexual, or HIV-positive sex partners currently or in past; persons seeking treatment for STDs; blood transfusion during 1978-1985.

HR3 = Persons infected with HIV, close contacts of persons with known or suspected TB, persons with medical risk factors associated with TB, immigrants from countries with high TB prevalence, medically underserved low-income populations (including homeless), residents of long-term care facilities.

~~**HR4** = Persons >2 yr living in areas where the disease is endemic and where periodic outbreaks occur (e.g., certain Alaska Native, Pacific Island, Native American, and religious communities). Consider for institutionalized children aged >2 yr. Clinicians should also consider local epidemiology.~~

~~HR5 -- Children aged 2 years or older with certain underlying medical conditions, including a cochlear implant.~~

~~HR6 -- Children aged 2 through 10 years with persistent complement component deficiency, anatomic or functional asplenia, and certain other conditions placing them at high risk.~~

Appendix C
Prevention Tables

HR~~7~~4 = Children about age 12 mo who: 1) live in communities in which the prevalence of lead levels requiring individual intervention, including residential lead hazard control or chelation, is high or undefined; 2) live in or frequently visit a home built before 1950 with dilapidated paint or with recent or ongoing renovation or remodeling; 3) have close contact with a person who has an elevated lead level; 4) live near lead industry or heavy traffic; 5) live with someone whose job or hobby involves lead exposure; 6) use lead-based pottery; or 7) take traditional ethnic remedies that contain lead.

HR~~8~~5 = Children living in areas with inadequate water fluoridation (<O.6 ppm).

HR~~9~~6 = Persons with a family history of skin cancer, a large number of moles, atypical moles, poor tanning ability, or light skin, hair, and eye color.

HR~~10~~7 = Having a: chronically mentally ill parent; substance abusing parent; mother who began parenting as a teen. Living at or below poverty. Having: parents involved in criminal behavior; experienced an out-of-home placement(s), multiple moves, failed adoption(s). Being homeless. Having suffered physical, emotional or sexual abuse, or severe neglect. Having: a chronic health problem in the family; an absence of a family support system. Being substance affected at birth.

Appendix C
Prevention Tables

Ages 11-24 Years

Interventions Considered and Recommended for the Periodic Health Examination

Leading Causes of Death
- Motor vehicle/other unintentional injuries
- Homicide
- Suicide
- Malignant neoplasms
- Heart diseases

Interventions for the General Population

SCREENING
- Height and weight
- Blood pressure[1]
- High-density lipoprotein cholesterol (HDL-C) and total blood cholesterol (age 20-24 if high-risk)[2]
- Papanicolaou (Pap) test[3]
- Chlamydia screen[4] (females <25 yr)
- Rubella serology or vaccination hx[5] (females >12 yr)
- Learning and attention disorders[6]
- Signs of child abuse, neglect, family violence
- Alcohol, inhalant, illicit drug use[7]
- Eating disorders[8]
- Anxiety and mood disorders[9]
- Suicide risk factors[10]

COUNSELING

Injury Prevention
- Lap/shoulder belts
- Bicycle/motorcycle/ATV helmet*
- Smoke detector*
- Safe storage/removal of firearms*
- Smoking near bedding or upholstery

Substance Use
- Avoid tobacco use
- Avoid underage drinking and illicit drug use*
- Avoid alcohol/drug use while driving, swimming, boating, etc.*

Sexual Behavior
- STD prevention: abstinence*; avoid high-risk behavior*; condoms/female barrier with spermicide*
- Unintended pregnancy: contraception

Diet and Exercise
- Limit fat and cholesterol; maintain caloric balance; emphasize grains, fruits, vegetables
- Adequate calcium intake (females)
- Regular physical activity*

Dental Health
- Regular visits to dental care provider*
- Floss, brush with fluoride toothpaste daily*

Mental Health/Chemical Dependency

Parent education regarding:
- Adolescent development
- Behavior management
- Effects of excess TV watching
- Special needs of child and family due to:
  - Familial stress or disruption
  - Health problems
  - Temperamental incongruence with parent
  - Environmental stressors such as community violence or disaster, immigration, minority status, ..homelessness
- Referral for MHCD and other family support services as indicated

[1]Periodic BP for persons aged ≥ 18 yr. [2]High-risk defined as having diabetes, family history of premature coronary disease or familial hyperlipidemia, or multiple cardiac risk factors. [3]Screening to start at age 21; screening should occur at least every 3 years. [4]If sexually active. [5]Serologic testing, documented vaccination history, and routine vaccination against rubella (preferably with MMR) are equally acceptable alternatives. [6]Consider screening with full DSM-IV criteria for attention deficit disorder, inattentive or hyperactive types, in children with significant overall academic or behavioral difficulty including academic failure and/or learning difficulty, especially in reading, math or handwriting. [7]Persons using alcohol and/or drugs. Physical and behavioral indicators: liver disease, pancreatitis, hypertension, gastritis, esophagitis, hematological disorders, poor nutritional status, cardiac arrhythmias, alcoholic myopathy, ketoacidosis, neurological disorders: smell of alcohol on breath, mood swings, memory lapses or losses, difficulty concentrating, blackouts, inappropriateness, irritability or agitation, depression, slurry speech, staggering gait, bizarre behavior, suicidal indicators, sexual dysfunction, interpersonal conflicts, domestic violence, child abuse and neglect, automobile accidents or citation arrests, scholastic or behavior problems, secretiveness or vagueness about personal or medical history. [8]Persons with a weight >10% below ideal body weight, parotid gland hypertrophy or erosion of tooth enamel. Females with a chemical dependency. [9]In women who are at increased risk, diagnostic evaluation should include an assessment of history of sexual and physical violence, interpersonal difficulties, prescription drug utilization, medical and reproductive history. [10]Recent divorce, separation, unemployment, depression, alcohol or other drug abuse, serious medical illness, living alone, homelessness, or recent bereavement.

*The ability of clinical counseling to influence this behavior is unproven.

Appendix C
Prevention Tables

Ages 11-24 Years (Cont'd)

Interventions for the General Population (Cont'd)

IMMUNIZATIONS

~~TDaP (11-16 yr)~~
~~Hepatitis B1~~
~~MMR (11-12 yr)2~~
~~Varicella (11-12 yr)3~~
~~Rubella4 (females >12 yr)~~
~~Influenza5~~
~~Polio6~~
~~Human papillomavirus (HPV)7~~
~~Meningococcal (11-12 yr) 8~~

CHEMOPROPHYLAXIS

Multivitamin with folic acid (females planning/ capable of pregnancy)

~~1If not previously immunized: current visit, 1 and 6 mo later. 2If no previous second dose of MMR. 3If susceptible to chickenpox. 4Serologic testing, documented vaccination history, and routine vaccination against rubella (preferably with MMR) are equally acceptable alternatives. 5Yearly (6 mo through 18 yrs). 6If not previously immunized. 7HPV2 and HPV4 for females aged 9 to 26. HPV4 for males aged 9 through 26. 8Children 13 through 18 if not previously vaccinated.~~

Interventions for the High-Risk Population

Screen for
- Syphilis RPR/VDRL (HR1);
- Gonorrhea (female) (HR2)
- HIV (HR3)
- Chlamydia (female) (HR4);
- Tuberculosis - PPD (HR3,5)

Advise to reduce infection risk (HR3,6)
~~Immunize with~~
- ~~Meningococcal vaccine (HR 7)~~
- ~~Pneumococcal polysaccharide vaccine (HR8)~~
- ~~Influenza vaccine (HR9)~~
- ~~Varicella vaccine (HR10)~~
- ~~MMR (HR12)~~
- ~~Hepatitis A vaccine (HR7)~~

Avoid excess/midday sun, use protective clothing* (HR~~12~~7)
Folic acid 4.0 mg (HR~~13~~8)
Daily fluoride supplement (HR~~14~~9)
Screen for child abuse, neurological, mental health conditions
Increased well-child/adolescent visits (HR~~15~~10)
Refer for genetic counseling and evaluation for BRCA testing by appropriately trained health care provider (HR~~16~~11).

High-Risk Groups

HR1 = Persons who exchange sex for money or drugs, and their sex partners; persons with other STDs (including HIV); and sexual contacts of persons with active syphilis. Clinicians should also consider local epidemiology.

HR2 = Females who have: two or more sex partners in the last year; a sex partner with multiple sexual contacts; exchanged sex for money or drugs; or a history of repeated episodes of gonorrhea. Clinicians should also consider local epidemiology.

HR3 = Males who had sex with males after 1975; past or present injection drug use; persons who exchange sex for money or drugs, and their sex partners; injection drug-using, bisexual or HIV-positive sex partner currently or in the past; blood transfusion during 1978-85; persons seeking treatment for STDs. Clinicians should also consider local epidemiology.

Appendix C
Prevention Tables

Ages 11-24 Years (Cont'd)

HR4 = Sexually active females with multiple risk factors including: history of prior STD; new or multiple sex partners; age < 25; nonuse or inconsistent use of barrier contraceptives; cervical ectopy. Clinicians should consider local epidemiology of the disease in identifying other high-risk groups.

HR5 = HIV positive, close contacts of persons with known or suspected TB, persons with medical risk factors associated with TB, immigrants from countries with high TB prevalence, medically underserved low-income populations (including homeless), alcoholics, injection drug users, and residents of long-term facilities.

HR6 = Persons who continue to inject drugs.

~~**HR7** = Children aged 11 through 12 years with persistent complement component deficiency, anatomic or functional asplenia, and certain other conditions placing them at high risk.~~

~~**HR8** =Immunocompetent persons with certain medical conditions, including chronic cardiopulmonary disorders, diabetes mellitus, and anatomic asplenia. Immunocompetent persons who live in high-risk environments/social settings (e.g., certain Native American and Alaska Native populations).~~

~~**HR9** = Annual vaccination of: residents of chronic care facilities; persons with chronic cardiopulmonary disorders, metabolic diseases (including diabetes mellitus), hemoglobinopathies, immunosuppression, or renal dysfunction.~~

~~**HR10** = Healthy persons aged >13 yr without a history of chickenpox or previous immunization. Consider serologic testing for presumed susceptible persons aged >13 yr.~~

~~**HR11** = Persons born after 1956 who lack evidence of immunity to measles or mumps (e.g., documented receipt of live vaccine on or after the first birthday, laboratory evidence of immunity, or a history of physician-diagnosed measles or mumps).~~

HR~~12~~7 = Persons with a family or personal history of skin cancer, a large number of moles, atypical moles, poor tanning ability, or light skin, hair, and eye color.

HR~~13~~8 = Women with prior pregnancy affected by neural tube defect planning a pregnancy.

HR~~14~~9 = Persons aged <17 yr living in areas with inadequate water fluoridation (<0.6 ppm).

HR1~~5~~0 = Having a: chronically mentally ill parent; substance abusing parent; mother who began parenting as a teen. Living at or below poverty. Having: parents involved in criminal behavior; experienced an out-of-home placement(s), multiple moves, failed adoption(s). Being homeless. Having suffered physical, emotional or sexual abuse, or severe neglect. Having: a chronic health problem in the family; an absence of a family support system. Being substance affected at birth.

Appendix C
Prevention Tables

Ages 11-24 Years (Cont'd)

HR1~~6~~1 = A family history of breast or ovarian cancer that includes a relative with a known deleterious mutation in BRCA1 or BRCA2 genes; two first-degree relatives with breast cancer, one of whom received the diagnosis at age 50 years or younger; a combination of three or more first- or second-degree relatives with breast cancer regardless of age at diagnosis; a combination of both breast and ovarian cancer among first- and second-degree relatives; a first-degree relative with bilateral breast cancer; a combination of two or more first- or second-degree relatives with ovarian cancer regardless of age at diagnosis; a first- or second-degree relative with both breast and ovarian cancer at any age; and a history of breast cancer in a male relative. For women of Ashkenazi Jewish heritage, an increased risk family history risk includes any first-degree relative (or two second-degree relatives on the same side of the family) with breast or ovarian cancer.

Appendix C
Prevention Tables

Ages 25-64 Years

Interventions Considered and Recommended for the Periodic Health Examination

Leading Causes of Death
- Malignant neoplasms
- Heart diseases
- Motor vehicle/other unintentional injuries
- Human immunodeficiency virus infection
- Suicide and homicide

Interventions for the General Population

SCREENING
Blood pressure
Height and weight
High-density lipoprotein cholesterol (HDL-C) and total blood cholesterol (men age 35-64, women age 45-64, all age 25-64 if high-risk[1])
Papanicolaou (Pap) test[2]
Fecal occult blood test (FOBT) and/or flexible sigmoidoscopy, or colonoscopy (>50 yr)[3]
Mammogram [5] (women 40-74 yrs)
Rubella serology or vaccination hx[5] (women of childbearing age)
Bone density measurement (women age 60-64 if high-risk)[6]
Fasting plasma glucose for patients with hypertension or hyperlipidemia
Learning and attention disorders[7]
Signs of child abuse, neglect, family violence
Alcohol, inhalant, illicit drug use[8]
Eating disorders[9]
Anxiety and mood disorders[10]
Suicide risk factors[11]
Somatoform disorders[12]
Environmental stressors[13]

COUNSELING
Substance Use
Tobacco cessation
Avoid alcohol/drug use while driving, swimming, boating, etc.*

Diet and Exercise
Limit fat and cholesterol; maintain caloric balance; emphasize grains, fruits, vegetables
Adequate calcium intake (women)
Regular physical activity*

Injury Prevention
Lap/shoulder belts
Bicycle/motorcycle/ATV helmet*
Smoke detector*
Safe storage/removal of firearms*
Smoking near bedding or upholstery

Sexual Behavior
STD prevention: abstinence*; avoid high-risk behavior*; condoms/female barrier with spermicide*
Unintended pregnancy: contraception

Dental Health
Regular visits to dental care provider*
Floss, brush with fluoride toothpaste daily*

~~**IMMUNIZATIONS**~~
~~TDaP boosters~~[14]
~~Human papillomavirus (HPV)~~[15]
~~Rubella~~[5] ~~(women of childbearing age)~~
~~Zoster (60 or older~~)

CHEMOPROPHYLAXIS
Multivitamin with folic acid (females planning or capable of pregnancy)
Discuss aspirin prophylaxis for those at high-risk for coronary heart disease

[1]High-risk defined as having diabetes, family history of premature coronary disease or familial hyperlipidemia, or multiple cardiac risk factors. [2]Women who are or have been sexually active and who have a cervix: q < 3 yr. [3] FOBT: annually; flexible sigmoidoscopy: every 5 years; colonoscopy: every 10 years. [4]The screening decision for women 40-49 should be a mutual decision between a woman and her clinician. If a decision to proceed with mammography is made, it should be done every 2 years. [5] Between the ages of 50-74, screening mammography should be performed every 2 years. [6]Serologic testing, documented vaccination history, and routine vaccination (preferably with MMR) are equally acceptable. [6]High-risk defined as weight <70kg, not on estrogen replacement. [7]Consider screening with full DSM-IV criteria for attention deficit disorder, inattentive or hyperactive types, in children with significant overall academic or behavioral difficulty including academic failure and/or learning difficulty, especially in reading, math or handwriting. [8]Persons using alcohol and/or drugs. Physical and behavioral indicators: liver disease, pancreatitis, hypertension, gastritis, esophagitis, hematological disorders, poor nutritional status, cardiac arrhythmias, alcoholic myopathy, ketoacidosis, neurological disorders: smell of alcohol on breath, mood swings, memory lapses or losses, difficulty concentrating, blackouts, inappropriateness, irritability or agitation, depression, slurry speech, staggering gait, bizarre behavior, suicidal indicators, sexual dysfunction, interpersonal conflicts, domestic violence, child abuse and neglect, automobile accidents or citation arrests, scholastic or behavior problems, secretiveness or vagueness about personal or medical history. [9]Persons with a weight >10% below ideal body weight, parotid gland hypertrophy or erosion of tooth enamel. Females with a chemical dependency. [10]In women who are at increased risk, diagnostic evaluation should include an assessment of history of sexual and physical violence, interpersonal difficulties, prescription drug utilization, medical and reproductive history. [11]Recent divorce, separation,

unemployment, depression, alcohol or other drug abuse, serious medical illness, living alone, homelessness, or recent bereavement. [12]Multiple unexplained somatic complaints. [13]Community violence or disaster, immigration, homelessness, family medical problems. ~~[14] One time TDaP dose to substitute for Td booster; then boost with Td every 10 years.~~ ~~[15]HPV2 and HPV4 for women aged 19 through 26. Discussion with provider regarding HPV4 for males aged 19 through 26.~~

*The ability of clinical counseling to influence this behavior is unproven.

Appendix C
Prevention Tables

Ages 25-64 Years (Cont'd)

Interventions for the High-Risk Population	
RPR/VDRL (HR1); screen for gonorrhea (female) (HR2), HIV (HR3), chlamydia (female) (HR4);	~~vaccine, (HR12); meningococcal vaccine (HR16)~~
PPD (HR~~7~~5) advice to reduce Infection risk (HR~~8~~6)	Avoid excess/midday sun, use protective clothing* (HR~~13~~7) Folic acid 4.0 mg (HR~~14~~8) Refer for genetic counseling and evaluation for BRCA testing by appropriately trained health care provider (HR~~15~~9)
~~Hepatitis B vaccine (HR5); Hepatitis A vaccine (HR6); pneumococcal polysaccharide vaccine (HR9); influenza vaccine (HR10); MMR (HR11); varicella~~	

High Risk Groups

HR1 = Persons who exchange sex for money or drugs, and their sex partners; persons with other STDs (including HIV); and sexual contacts of persons with active syphilis. Clinicians should also consider local epidemiology.

HR2 = Women who exchange sex for money or drugs, or who have had repeated episodes of gonorrhea. Clinicians should also consider local epidemiology.

HR3 = Males who had sex with males after 1975; past or present injection drug use; persons who exchange sex for money or drugs, and their sex partners; injection drug-using, bisexual or HIV-positive sex partner currently or in the past; blood transfusion during 1978-1985; persons seeking treatment for STDs. Clinicians should also consider local epidemiology.

HR4 = Sexually active women with multiple risk factors including: history of STD; new or multiple sex partners; nonuse or inconsistent use of barrier contraceptives; cervical ectopy. Clinicians should consider local epidemiology.

~~**HR5** = Blood product recipients (including hemodialysis patients), men who have sex with men, injection drug users and their sex partners, persons with multiple recent sex partners, persons with other STDs (including HIV).~~

~~**HR6** = Persons living in areas where the disease is endemic and where periodic outbreaks occur (e.g., certain Alaska Native, Pacific Island, Native American, and religious communities); men who have sex with men; injection or street drug users. Consider for institutionalized persons. Clinicians should also consider local epidemiology.~~

Appendix C
Prevention Tables

Ages 25-64 Years (Cont'd)

HR~~7~~5 = HIV positive, close contacts of persons with known or suspected TB, persons with medical risk factors associated with TB, immigrants from countries with high TB prevalence, medically underserved low-income populations (including homeless), alcoholics, injection drug users, and residents of long-term facilities.

HR~~8~~6 = Persons who continue to inject drugs.

~~**HR9** = Immunocompetent institutionalized persons >50 yr and immunocompetent with certain medical conditions, including chronic cardiac or pulmonary disease, diabetes mellitus, and anatomic asplenia. Immunocompetent persons who live in high-risk environments or social settings (e.g., certain Native American and Alaska Native populations).~~

~~**HR10** = Annual vaccination of residents of chronic care facilities; persons with chronic cardiopulmonary disorders, metabolic diseases (including diabetes mellitus), hemoglobinopathies, immunosuppression or renal dysfunction.~~

~~**HR11** = Persons born after 1956 who lack evidence of immunity to measles or mumps (e.g., documented receipt of live vaccine on or after the first birthday, laboratory evidence of immunity, or a history of physician-diagnosed measles or mumps).~~

~~**HR12** = Healthy adults without a history of chickenpox or previous immunization. Consider serologic testing for presumed susceptible adults.~~

HR~~13~~7 = Persons with a family or personal history of skin cancer, a large number of moles, atypical moles, poor tanning ability, or light skin, hair, and eye color.

HR~~14~~8 = Women with previous pregnancy affected by neural tube defect who are planning pregnancy.

HR~~15~~9 = A family history of breast or ovarian cancer that includes a relative with a known deleterious mutation in BRCA1 or BRCA2 genes; two first-degree relatives with breast cancer, one of whom received the diagnosis at age 50 years or younger; a combination of 3 or more first- or second-degree relatives with breast cancer regardless of age at diagnosis; a combination of both breast and ovarian cancer among first- and second-degree relatives; a first-degree relative with bilateral breast cancer; a combination of two or more first- or second-degree relatives with ovarian cancer regardless of age at diagnosis; a first- or second-degree relative with both breast and ovarian cancer at any age; and a history of breast cancer in a male relative. For women of Ashkenazi Jewish heritage, an increased risk family history risk includes any first-degree relative (or two second-degree relatives on the same side of the family) with breast or ovarian cancer.

~~HR16 = Adults with anatomic or functional asplenia or persistent complement component deficiencies; first year college students living in dormitories, military recruits~~

Appendix C
Prevention Tables

Age 65 and Older

Interventions Considered and Recommended for the Periodic Health Examination	Leading Causes of Death
	Heart diseases
	Malignant neoplasms (lung, colorectal, breast)
	Cerebrovascular disease
	Chronic obstructive pulmonary disease
	Pneumonia and influenza

Interventions for the General Population

SCREENING
Blood pressure
Height and weight
Fecal occult blood test (FOBT) and/or flexible sigmoidoscopy or colonoscopy t.[1]
Mammogram (women ages 65-74) [2]
Bone density measurement (women)
Fasting plasma glucose for patients with hypertension or hyperlipidemia
Vision screening
Assess for hearing impairment
Signs of elder abuse, neglect, family violence
Alcohol, inhalant, illicit drug use[3]
Anxiety and mood disorders[4]
Somatoform disorders[5]
Environmental stressors[6]
Abdominal aortic aneurysm (AAA) (men aged 65 to 75 who have ever smoked)[7]

COUNSELING
Substance Use
Tobacco cessation
Avoid alcohol/drug use while driving, swimming, boating, etc.*

Diet and Exercise
Limit fat and cholesterol; maintain caloric balance; emphasize grains, fruits, vegetables
Adequate calcium intake (women)
Regular physical activity*
Assess eating environment

Injury Prevention
Lap/shoulder belts
Motorcycle and bicycle helmets*
Fall prevention*
Safe storage/removal of firearms*
Smoke detector*
Set hot water heater to <120-130°F
CPR training for household members
Smoking near bedding or upholstery

Dental Health
Regular visits to dental care provider*
Floss, brush with fluoride toothpaste daily*
Sexual Behavior
STD prevention: avoid high-risk sexual behavior*; use condoms

~~**IMMUNIZATIONS**~~
~~Pneumococcal vaccine~~
~~Influenza~~[8]
~~Tetanus-diphtheria (Td) boosters~~
~~Zoster vaccine~~

CHEMOPROPHYLAXIS
Discuss aspirin prophylaxis for those at high-risk for coronary heart disease

[1]FOBT: annually; flexible sigmoidoscopy: every 5 years; colonoscopy: every 10 years through age 75. [2]Screening mammography should be performed every 2 years. [3]Persons using alcohol and/or drugs. Physical and behavioral indicators: liver disease, pancreatitis, hypertension, gastritis, esophagitis, hematological disorders, poor nutritional status, cardiac arrhythmias, alcoholic myopathy, ketoacidosis, neurological disorders: smell of alcohol on breath, mood swings, memory lapses or losses, difficulty concentrating, blackouts, inappropriateness, irritability or agitation, depression, slurry speech, staggering gait, bizarre behavior, suicidal indicators, sexual dysfunction, interpersonal conflicts, domestic violence, child abuse and neglect, automobile accidents or citation arrests, scholastic or behavior problems, secretiveness or vagueness about personal or medical history. [4]In women who are at increased risk, diagnostic evaluation should include an assessment of history of sexual and physical violence, interpersonal difficulties, prescription drug utilization, medical and reproductive history. 5Multiple unexplained somatic complaints. [6]Community violence or disaster, immigration, homelessness, family medical problems. [7]One-time ultrasound. [8]~~Annually.~~

*The ability of clinical counseling to influence this behavior is unproven

Appendix C
Prevention Tables

Age 65 and Older (Cont'd)

Interventions for the High-Risk Population	
PPD (HR1); amantadine/rimantadine (HR~~4~~3)	HIV screen (HR~~3~~2); ~~hepatitis B vaccine (HR8)~~ RPR/VDRL (HR~~9~~7) Advice to reduce Infection risk (HR~~10~~8)
Fall prevention intervention (HR~~5~~4) Consider cholesterol screening (HR~~6~~5) Avoid excess/midday sun, use protective clothing* (HR~~7~~6); ~~hepatitis A vaccine (HR2)~~	~~Varicella vaccine (HR11)~~ Refer to meal and social support resources Refer for genetic counseling and evaluation for BRCA testing by appropriately trained health care provider (HR~~12~~9)

High Risk Groups

HR1 = HIV positive, close contacts of persons with known or suspected TB, persons with medical risk factors associated with TB, immigrants from countries with high TB prevalence, medically underserved low-income populations (including homeless), alcoholics, injection drug users, and residents of long-term facilities.

~~**HR2** = Persons living in areas where the disease is endemic and where periodic outbreaks occur (e.g., certain Alaska Native, Pacific Island, Native American, and religious communities); men who have sex with men; injection or street drug users. Consider for institutionalized. Clinicians should also consider local epidemiology.~~

HR~~3~~2 = Men who had sex with males after 1975; past or present injection drug use; persons who exchange sex for money or drugs, and their sex partners; injection drug-using, bisexual or HIV-positive sex partner currently or in the past; blood transfusion during 1978-1985; persons seeking treatment for STDs. Clinicians should also consider local epidemiology.

HR~~4~~3 = Consider for persons who have not received influenza vaccine or are vaccinated late; when the vaccine may be ineffective due to major antigenic changes in the virus; to supplement protection provided by vaccine in persons who are expected to have a poor antibody response; and for high-risk persons in whom the vaccine is contraindicated.

HR~~5~~4 = Persons aged 75 years and older; or aged 70-74 with one or more additional risk factors including: use of certain psychoactive and cardiac medications (e.g., benzodiazepines, antihypertensives); use of >4 prescription medications; impaired cognition, strength, balance, or gait. Intensive individualized home-based multifactorial fall prevention intervention is recommended in settings where adequate resources are available to deliver such services.

HR~~6~~5 = Although evidence is insufficient to recommend routine screening in elderly persons, clinicians should consider cholesterol screening on a case-by-case basis for persons ages 65-75 with additional risk factors (e.g., smoking, diabetes, or hypertension).

HR~~7~~6 = Persons with a family or personal history of skin cancer, a large number of moles, atypical moles, poor tanning ability, or light skin, hair, and eye color.

~~**HR8** = Blood product recipients (including hemodialysis patients), men who have sex with men, injection drug users and their sex partners, persons with multiple recent sex partners, persons with other STDs (including HIV).~~

Appendix C
Prevention Tables

HR~~9~~7 = Persons who exchange sex for money or drugs, and their sex partners; persons with other STDs (including HIV); and sexual contacts of persons with active syphilis. Clinicians should also consider local epidemiology.

HR~~10~~8 = Persons who continue to inject drugs.

~~**HR11** = Healthy adults without a history of chickenpox or previous immunization. Consider serologic testing for presumed susceptible adults.~~

HR~~12~~9 = A family history of breast or ovarian cancer that includes a relative with a known deleterious mutation in BRCA1 or BRCA2 genes; two first-degree relatives with breast cancer, one of whom received the diagnosis at age 50 years or younger; a combination of three or more first- or second degree relatives with breast cancer regardless of age at diagnosis; a combination of both breast and ovarian cancer among first- and second- degree relatives; a first-degree relative with bilateral breast cancer; a combination of two or more first- or second-degree relatives with ovarian cancer regardless of age at diagnosis; a first- or second-degree relative with both breast and ovarian cancer at any age; and a history of breast cancer in a male relative. For women of Ashkenazi Jewish heritage, an increased family history risk includes any first-degree relative (or two second degree relatives on the same side of the family) with breast or ovarian cancer.

Appendix C
Prevention Tables

Pregnant Women**

Interventions Considered and Recommended for the Periodic Health Examination

Interventions for the General Population

First visit
Blood pressure
Hemoglobin/hematocrit
Hepatitis B surface antigen (HBsAg)
RPR/VDRL
Chlamydia screen (<25 yr)
Rubella serology or vaccination history
D(Rh) typing, antibody screen
Offer CVS (<13 wk)[1] or amniocentesis (15-18 wk)[1] (age>35 yr)
Offer hemoglobinopathy screening
Assess for problem or risk drinking
HIV screening

Follow-up visits
Blood pressure
Urine culture (12-16 wk)
Screening for gestational diabetes[2]
Offer amniocentesis (15-18 wk)[1] (age>35 yr)
Offer multiple marker testing[1] (15-18 wk)
Offer serum α-fetoprotein[1] (16-18 wk)

COUNSELING
Tobacco cessation; effects of passive smoking
Alcohol/other drug use
Nutrition, including adequate calcium intake Encourage breastfeeding
Lap/shoulder belts
Infant safety car seats
STD prevention: avoid high-risk sexual behavior*; use condoms*

CHEMOPROPHYLAXIS
Multivitamin with folic acid[3]

[1]Women with access to counseling and follow-up services, reliable standardized laboratories, skilled high-resolution ultrasound, and, for those receiving serum marker testing, amniocentesis capabilities. [2]Universal screening is recommended for areas (states, counties, or cities) with an increased prevalence of HIV infection among pregnant women. In low-prevalence areas, the choice between universal and targeted screening may depend on other considerations (see Ch. 28). [3]Beginning at least 1 mo before conception and continuing through the first trimester..

*The ability of clinical counseling to influence this behavior is unproven.

**See tables for ages 11-24 and 25-64 for other preventive services recommended for women of these age groups.

Appendix C
Prevention Tables

Pregnant Women (Cont'd)

Interventions for the High-Risk Population

POPULATION	POTENTIAL INTERVENTIONS (See detailed high-risk definitions)
High-risk sexual behavior	Screen for chlamydia (1st visit) (HR1), gonorrhea (1st visit) (HR2); ~~HIV (1st visit) (HR3);~~
Injection drug use	HBsAg (3rd trimester) (HR~~4~~3); RPR/VDRL (3rd trimester) (HR~~5~~4); HBsAg (3rd trimester) (HR~~4~~3); advice to reduce infection risk (HR~~6~~5);
Unsensitized D-negative women	D(Rh) antibody testing (24-28 wk) (HR~~7~~6)
Risk factors for Down syndrome	Offer CVS[1] (1st trimester), amniocentesis[1] (15-18 wk) (HR~~8~~7)
Previous pregnancy with neural tube defect	Offer amniocentesis[1] (15-18 wk), folic acid 4.0 mg[3] (HR~~9~~8)
High risk for child abuse	Targeted case management

Appendix C

High Risk Groups

HR1 = Women with history of STD or new or multiple sex partners. Clinicians should also consider local epidemiology. Chlamydia screen should be repeated in 3rd trimester if at continued risk.

HR2 = Women under age 25 with two or more sex partners in the last year, or whose sex partner has multiple sexual contacts; women who exchange sex for money or drugs; and women with a history of repeated episodes of gonorrhea. Clinicians should also consider local epidemiology. Gonorrhea screen should be repeated in the 3rd trimester if at continued risk.

~~**HR3** = Women who are initially HBsAg negative who are at high risk due to injection drug use, suspected exposure to hepatitis B during pregnancy, multiple sex partners~~

HR~~4~~3 = Women who are initially HBsAg negative who are at high risk due to injection drug use, suspected exposure to hepatitis B during pregnancy, multiple sex partners

HR~~5~~4 = Women who exchange sex for money or drugs, women with other STDs (including HIV), and sexual contacts of persons with active syphilis. Clinicians should also consider local epidemiology

HR~~6~~5 = Women who continue to inject drugs

HR~~7~~6 = Unsensitized D-negative women

HR~~8~~7 = Prior pregnancy affected by Down syndrome, advanced maternal age (>35 yr), known carriage of chromosome rearrangement

HR~~9~~8 = Women with previous pregnancy affected by neural tube defect

Section 3

Staff Report

October 2012 VBBS

The acupuncture guideline was changed to add low back pain as a covered diagnosis. The guideline wording that was approved had ICD-10 codes rather than ICD-9 codes. The guideline change is scheduled to take effect April 1, 2013 and therefore needs the corresponding ICD-9 codes. The ICD-10 coding will be implemented with the October 1, 2014 Prioritized List (tentative)

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,212,435,563

Line 1 PREGNANCY

Acupuncture (97810-97814) pairs on Line 1 for the following conditions and codes.

Hyperemesis gravidarum

ICD-9 codes: 643.00, 643.03, 643.10, 643.11, 643.13

Acupuncture for hyperemesis gravidarum is covered when a diagnosis is made by the maternity care provider and referred for acupuncture treatment. Up to 2 sessions of acupressure/acupuncture are covered.

Breech presentation

ICD-9 codes: 652.20, 652.23

Acupuncture (and moxibustion) for breech presentation is covered when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 2 visits.

Back and pelvic pain of pregnancy

ICD-9 codes: 648.70, 648.73

Acupuncture is covered for back and pelvic pain of pregnancy when referred by maternity care provider/primary care provider for up to 12 sessions.

Line 212 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Acupuncture is covered on this line for the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time an limited to 15 total sessions, with documentation of meaningful improvement.

Line 400 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT

Acupuncture (97810-4) is included on Line 400 only for pairing with disorders of the spine with myelopathy and/or radiculopathy represented by the diagnosis codes (344.60, 722.1, 722.2, 722.7, 724.4) ~~M47.26, M47.27, M51.06, M51.07, M51.16, M51.17, M51.26, M51.27, M54.16, M54.17~~. Acupuncture for the treatment of these conditions is only covered, when referred, for up to 12 sessions.

Line 435 MIGRAINE HEADACHES

Acupuncture pairs on Line 435 for ICD-9 346, when referred, for up to 12 sessions.

Line 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT

Acupuncture pairs on Line 562 only with the low back diagnoses ((344.60, 722.1, 722.2, 722.7, 724.4) ~~M47.816, M47.817, M47.896, M47.897, M48.36, M48.37, M51.26,~~

~~M51.27, M51.36, M51.37, M51.86, M51.87, M54.5, M62.830, S33.5xxA, S33.9xxA, S39.092A, S39.82xA, S39.93xA~~), when referred, for up to 12 sessions.

Line 563 TENSION HEADACHES

Acupuncture is included on Line 563 for treatment of tension headaches, when referred, for up to 12 sessions.

December 2012

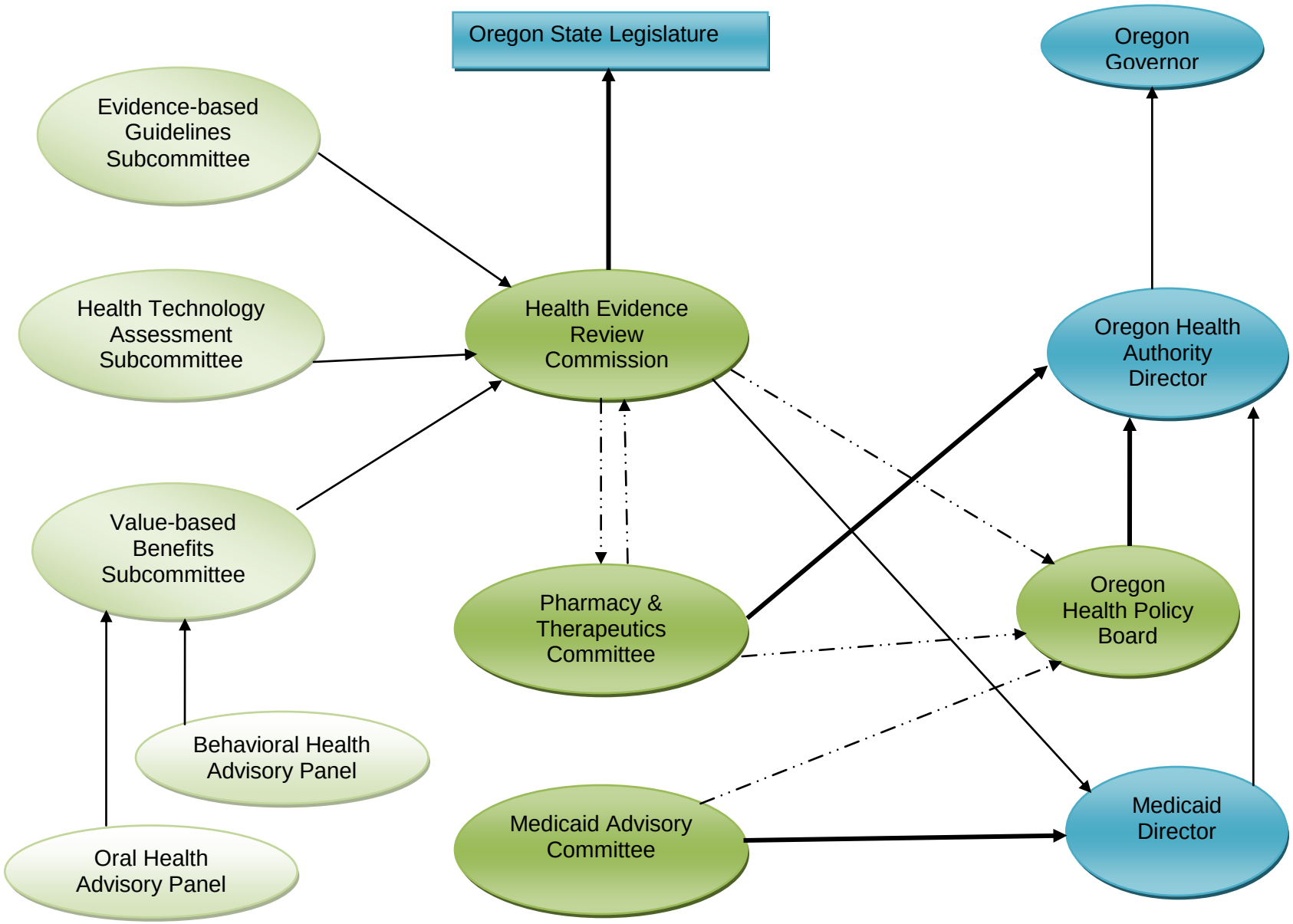
A. Coding specifications for cognitive behavioral therapy (CBT) were modified to contain ICD-9 codes for implementation with the April 1, 2013 List. However, the CPT code correction for the October 1, 2013 ICD-10 List was presented incorrectly in the meeting materials and in the minutes. The following are the correct coding specification changes that need to be made: NOTE: there is an agenda item which would eliminate this coding change entirely. This recommendation may therefore be moot.

1) Add the following coding recommendation to Line 400 for the April 1, 2013 Prioritized List
   a. Cognitive behavioral therapy (90785-90840) only pairs on Line 400 with the low back diagnoses (344.60, 722.1, 722.2, 722.7, 724.4)
2) Add the following coding recommendation to Line 562 for the April 1, 2013 Prioritized List
   a. Cognitive behavioral therapy (90785-90840) only pairs on Line 562 with the low back diagnoses (720.2, 721.3, 721.7, 721.8, 721.90, 722.1, 722.2, 722.32, 722.39, 722.5, 722.6, 722.8, 722.9, 724.1, 724.2, 724.5-724.9, 739.2-739.4, 847.1-847.9).
3) Change the following coding recommendation for Line 400 for the October 1, 2014 ~~April 1, 2013~~ Prioritized List
   a. Cognitive behavioral therapy (90785-90840) only pairs on Line 400 with the low back diagnoses (~~344.60, 722.1, 722.2, 722.7, 724.4~~ M47.26, M47.27, M51.06, M51.07, M51.16, M51.17, M51.26, M51.27, M54.16, M54.17)
4) Change the following coding recommendation for Line 562 for the October 1, 2014 ~~April 1, 2013~~ Prioritized List
   a. Cognitive behavioral therapy (90785-90840) only pairs on Line 562 with the low back diagnoses (~~720.2, 721.3, 721.7, 721.8, 721.90, 722.1, 722.2, 722.32, 722.39, 722.5, 722.6, 722.8, 722.9, 724.1, 724.2, 724.5-724.9, 739.2-739.4, 847.1-847.9~~ M47.816, M47.817, M47.896, M47.897, M48.36, M48.37, M51.26, M51.27, M51.36, M51.37, M51.86, M51.87, M54.5, M62.830, S33.5xxA, S33.9xxA, S39.092A, S39.82xA, S39.93xA).

B. At the 2013 HCPCS code review, one code was not specifically discussed. This code was presented in the meeting materials. HERC staff has placed it on the Prioritized List as presented in the meeting materials for the April 1, 2013 List. Staff is confirming that this is indeed the recommended placement for this code:

> S9110 (Telemonitoring of patient in their home, including all necessary equipment; computer system, connections, and software; maintenance; patient education and support; per month).
> Recommended placement: Ancillary

OHA Committee Organization Chart



Section 4

Previously Discussed Items

Pseudobulbar Affect

Question: Should the prioritization of pseudobulbar affect be changed given the introduction of an FDA approved medication to treat this condition?

Question source: Avanir Pharmaceuticals

Issue:
Pseudobulbar affect (PBA) refers to a neurologic disorder characterized by involuntary crying or uncontrollable episodes of crying and/or laughing, or other emotional displays. PBA occurs secondary to neurologic disease or brain injury. PBA is also known as emotional lability or labile affect. Traditionally, antidepressants such as fluoxetine, citalopram, or amitriptyline have been prescribed with moderate efficacy. In 2010, a combination of dextromethorphan and quinidine was approved by the U.S. Food and Drug Administration (FDA) for the treatment of PBA. The drug, Nuedexta, was developed and created by Avanir Pharmaceuticals and became available on January 31, 2011.

Currently, pseudobulbar affect (ICD-9 310.81) is on line 687 NEUROLOGIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. VbBS considered reprioritization of this condition at the December, 2012 meeting. At that meeting, the literature on Neudexta was reviewed and testimony was received from representatives of Avanir Pharmaceuticals. The subcommittee requested that HERC staff obtain outside expert Neurology input on this topic. Staff was also directed to come up with a proposed new prioritization of PBA to help determine what other line might be appropriate for this condition.

Expert input: Ray Englander, MD, Neurology (January 11, 2013)

Approval of Neudexta for treatment of PBA was based on 1 or 2 decent studies with a small group of patients. The only patients included in these studies were patients with ALS or MS and PBA. Subsequently, the FDA has only approved Neudexta for treatment of PBA in these 2 types of patients; all other uses would be experimental. In Dr. Englander's opinion, only these two types of patients should be eligible for consideration for treatment with Neudexta. In Dr. Englander's practice, the majority of patients with PBA have stroke as their underlying diagnosis, or multisystem atrophy. Those patients with MS or ALS with PBA are advanced in their disease and have significant other disabilities, which limits how much treatment of their PBA can improve their quality of life. Dr. Englander does believe that the efficacy for treating PBA in ALS and MS patients is good, with about a 50% improvement in symptoms. He stresses, however, that this medication only treats the symptom, not the underlying condition (MS or ALS). Dr. Englander feels that treatment of PBA should be a low priority, as there are many other very effective treatments for other

conditions which should be funded first. This medication is very expensive and the money could be better spent on inexpensive, effective treatments for conditions like epilepsy. What other treatments or conditions would need to be cut to allow coverage of Neudexta?

Ranking recommendation for PBA (current scores for line 687 in parentheses)
These scores are as recommended in discussion with Dr. Englander
Category 7 (9)
Impact on Healthy Life Years 1 (2)
Impact on pain and suffering 2 (2)
Population effects 0 (0)
Vulnerable populations 0 (0)
Tertiary prevention 0
Effectiveness 2 (0)
Need for treatment 0.5 (0)
Net cost 2 (0)
Score 60 which is approximately Line 580

Recommendation

1) Move pseudobulbar affect (ICD-9 310.81) from line 687 NEUROLOGIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY to line 569 IMPULSE DISORDERS EXCLUDING PATHOLOGICAL GAMBLING
    a. Similar prioritization scoring and similar diagnoses on this line
2) Consider adding the following guideline to lines 268 MULTIPLE SCLEROSIS AND OTHER DEMYELINATING DISEASES OF CENTRAL NERVOUS SYSTEM and 407 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION [ALS (ICD-9 335.20) is included only on the 4 dysfunction lines]

GUIDELINE NOTE XXX TREATMENT OF PSEUDOBULBAR AFFECT
Lines 268, 407, 687
Treatment of pseudobulbar affect (PBA) with dextromethorphan/quinidine is only covered for patients whose PBA is due to multiple sclerosis (MS) or amyotrophic lateral sclerosis (ALS).

Rank Order of Health Care Categories

1) Maternity & Newborn Care (100) - Obstetrical care for pregnancy. Prenatal care; delivery services; postpartum care; newborn care for conditions intrinsic to the pregnancy.

2) Primary Prevention and Secondary Prevention (95) - Effective preventive services used prior to the presence of disease and screenings for the detection of diseases at an early stage. Immunizations; fluoride treatment in children; mammograms; pap smears; blood pressure screening; well child visits; routine dental exams.

3) Chronic Disease Management (75) - Predominant role of treatment in the presence of an established disease is to prevent an exacerbation or a secondary illness. Medical therapy for diabetes mellitus, asthma, and hypertension. Medical/psychotherapy for schizophrenia.

4) Reproductive Services (70) - Excludes maternity and infertility services. Contraceptive management; vasectomy; tubal occlusion; tubal ligation.

5) Comfort Care (65) - Palliative therapy for conditions in which death is imminent. Hospice care; pain management.

6) Fatal Conditions, Where Treatment is Aimed at Disease Modification or Cure (40) - Appendectomy for appendicitis; medical & surgical treatment for treatable cancers; dialysis for end-stage renal disease; medical therapy for stroke; medical/psychotherapy for single episode major depression.

7) Nonfatal Conditions, Where Treatment is Aimed at Disease Modification or Cure (20) - Treatment of closed fractures; medical/psychotherapy for obsessive-compulsive disorders; medical therapy for chronic sinusitis.

8) Self-limiting conditions (5) - Treatment expedites recovery for conditions that will resolve on their own whether treated or not. Medical therapy for diaper rash, acute conjunctivitis and acute pharyngitis.

9) Inconsequential care (1) - Services that have little or no impact on health status due to the nature of the condition or the ineffectiveness of the treatment. Repair fingertip avulsion that does not include fingernail; medical therapy for gallstones without cholecystitis, medical therapy for viral warts.

Impact Healthy Life Years
+ Impact on Suffering
+ Population Effects X Effectiveness X Need for Service
+ Vulnerable of Population Affected
+ Tertiary Prevention (categories 6 & 7 only)

Population and Individual Impact Measures

Impact on Health Life Years - to what degree will the condition impact the health of the individual if left untreated, considering the median age of onset (i.e., does the condition affect mainly children, where the impacts could potentially be experienced over a person's entire lifespan)? Range of 0 (no impact) to 10 (high impact).

Impact on Suffering - to what degree does the condition result in pain and suffering? Effect on family members (e.g. dealing with a loved one with Alzheimer's disease or needing to care for a person with a life-long disability) should also be factored in here. Range of 0 (no impact) to 5 (high impact).

Population Effects - the degree to which individuals other than the person with the illness will be affected. Examples include public health concerns due the spread of untreated tuberculosis or public safety concerns resulting from untreated severe mental illness. Range of 0 (no effects) to 5 (widespread effects).

Vulnerability of Population Affected - to what degree does the condition affect vulnerable populations such as those of certain racial/ethnic decent or those afflicted by certain debilitating illnesses such as HIV disease or alcohol & drug dependence? Range of 0 (no vulnerability) to 5 (high vulnerability).

Tertiary Prevention - in considering the ranking of services within new categories 6 and 7, to what degree does early treatment prevent complications of the disease (not including death)? Range of 0 (doesn't prevent complications) to 5 (prevents severe complications).

Effectiveness - to what degree does the treatment achieve its intended purpose? Range of 0 (no effectiveness) to 5 (high effectiveness).

Need for Medical Services - the percentage of time in which medical services would be required after the diagnosis has been established. Percentage from 0 (services never required) to 1 (services always required).

Net Cost - the cost of treatment for the typical case (including lifetime costs associated with chronic diseases) minus the expected costs if treatment is not provided -- including costs incurred through safety net providers (e.g., emergency departments) for urgent or emergent care related to the injury/illness or resulting complications. Range of 0 (high net cost) to 5 (cost saving).

Section 5

New Discussion Items

Uterine Artery Embolization

Question: Should uterine artery embolization (UAE) be added to the Prioritized List for treatment of dysfunctional uterine bleeding caused by uterine fibroids?

Question source: Mary Costantino, MD

Issue: Fibroid tumors on the uterus can result in significant bleeding, pain, and reduction in quality of life. Currently, fibroids (ICD-9 218.9, Leiomyoma of uterus, unspecified) are on line 428 UTERINE LEIOMYOMA. Various treatments, including D&C, myomectomy, and hysterectomy are included on this line. Dr. Costantino has requested that the HERC review the use of uterine artery embolization for treatment of fibroids. UAE is a radiologic procedure in which the blood supply to the fibroid is blocked, shrinking the tumor and reducing the bleeding and other complications. Currently, uterine artery embolization (CPT 37210) is on the Excluded List. This issue was last reviewed in 2003. At that time, UAE was felt to be much more costly than hysterectomy and was not adopted as a treatment option.

HOSC December, 2003

> There was discussion regarding code 37204, embolization of fibroids. Dr. Sohl reported that it is quite effective, but very expensive. Dr. Glass asked what the indications are for this procedure rather than a hysterectomy. He responded that it is a matter of patient preference for preserving their uterus and/or fertility. He was unaware of any difference in outcome, but there is a long-term concern for recurrence. Dr. Glass asked if this procedure would be used to preserve fertility or restore fertility. Dr. Sohl responded normally the former, but in the case of a large submucous fibroid that resulted in inadequate uterine volume, it could be the latter. Its benefit over myomectomy is that it is non-invasive, and has reduced surgical risk and post-operative scarring. Dr. Little stated her concern that this was similar to Essure, the product that achieves tubal ligation non-invasively, but at a higher cost due to a high failure rate, which the Commission has recommended not placing on the List. She felt the two issues should be treated consistently. It was noted that this code appears on several other lines, as the code is not specific to the uterus. Dr. Sohl would like to see an option of coverage for patients who are very poor surgical risks. He also suggested finding out if the costs have decreased, as his memory is that it costs approximately $20,000. Addition of a guideline was discussed, but ultimately it was decided to not place this code on the fibroid line.

Dr. Costatino sent an extensive list of articles on this topic (see attached bibliography). Any papers in this bibliography not included in this packet are available on request from HERC staff.

Uterine Artery Embolization

Evidence

1) **Gupta 2012**, Cochrane review of uterine artery embolization
    a. N=6 RCTs (732 women)
    b. Compared UAE with myomectomy or hysterectomy
    c. Moderately good evidence that there is no significant difference between UAE and surgery in patient satisfaction rates up to 5 years
    d. Very low level evidence that quality of life improved equally with UAE and surgery
    e. Very low level evidence that myomectomy is associated with better fertility outcomes than UAE
    f. No significant difference in rate of major complications between UAE and surgery
    g. UAE significant reduced length of hospital stay and need for blood transfusion
    h. UAE associated with higher rates of minor short and long term complications, unscheduled readmissions, and increased surgical reintervention rates
2) **NICE 2010**, Summary of review of UAE for fibrods
    a. Current evidence on uterine artery embolisation (UAE) for fibroids shows that the procedure is efficacious for symptom relief in the short and medium term for a substantial proportion of patients. There are no major safety concerns. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance and audit.
    b. A register of 1387 patients reported that 84% and 83% of patients had an improvement in their symptoms after UAE at 6 and 24 months respectively. The register of 1387 patients reported an improvement in mean health-related quality of life scores (on a scale from 0 to 100) from 44.1 at baseline to 79.5 after UAE at a maximum 3-year follow-up ($p < 0.001$).
    c. In a register of 2112 patients, the mean symptom score (on a scale from 0 to 100) improved from 58.6 at baseline to 16.5 among 1218 patients at 3-year follow-up ($p < 0.001$).
    d. A randomised controlled trial (RCT) of 157 patients treated by UAE or surgery (hysterectomy or myomectomy) reported symptom improvement in both groups, but this improvement was significantly greater among patients treated by surgery than by UAE ($p = 0.004$ at 1 month, $p = 0.03$ at 12 months).
    e. The register of 1387 patients reported a mean uterine volume reduction of 40% ($n = 666$) and a mean reduction in fibroid diameter of 2.2 cm ($n = 847$).
    f. The register of 2112 patients reported a re-intervention rate of 15% during a 3-year follow-up (10% hysterectomy, 3% myomectomy and 2% repeat UAE).

g. An RCT of 177 patients treated by UAE or hysterectomy reported that 28% (23/81) of UAE-treated patients had required hysterectomy at 5-year follow-up.
h. Uterine infection was reported in 2% (28/1387) of patients in one of the registers. Septic shock and multiple organ failure leading to death 25 days after UAE occurred in 1 patient in a case series of 21 patients, reported in a systematic review of 36 papers. Septicaemia and emergency myomectomy or hysterectomy were reported in 3% (17/649) of UAE-treated patients in a non-randomised comparative study of 1108 patients. Arterial dissection or perforation were reported in 2 patients, groin bleeding or pseudoaneurysm were reported in 2 patients, and femoral artery occlusion was reported in 1 patient from the register of 1387 patients. One case of bowel perforation treated by laparotomy was reported in the register of 1387 patients. A severe vasovagal event requiring atropine was reported in 1 out of 106 UAE-treated patients in the RCT of 157 patients.

3) **Moss 2011**, REST study for long term outcomes of UAE vs surgery
   a. RCT, 27 centers in UK
   b. N=127 women
   c. There were no significant differences between groups in any of the eight components of the SF-36 scores at 5 years (minimum P = 0.45). Symptom score reduction and patient satisfaction with either treatment was very high, with no group difference. Rates of adverse events were similar in both groups (19% embolization and 25% surgery; P = 0.40). The 5-year intervention rate for treatment failure or complications was 32% (UAE arm) and 4% (surgery arm), respectively. The initial cost benefit of UAE over surgery at 12 months was substantially reduced because of subsequent interventions, with treatments being cost neutral at 5 years.
   d. Conclusions We have found that UAE is a satisfactory alternative to surgery for fibroids. The less invasive nature of UAE needs to be balanced against the need for re-intervention in almost a third of patients. The choice should lie with the informed patient.

1) **Manyonda 2012**, QALY study of UAE vs myomectomy
   a. UAE patients had shorter hospitalization (2 vs. 6 days, p\0.001). By 1 year postintervention, significant and equal improvements in QoL scores had occurred in both groups (myomectomy n = 59; UAE n = 61). There had been two (2.9%) major complications among UAE versus 6 (8%) among myomectomy patients (not significant). By 2 years, among UAE patients (n = 57) there were eight (14.0%) reinterventions for inadequate symptom control compared with one (2.7%) among myomectomy patients (n = 37). Half of the women who required hysterectomy had concomitant adenomyosis missed by US

   b. Conclusions UAE and myomectomy both result in significant and equal improvements in QoL. UAE allows a shorter hospital stay and fewer major complications but with a higher rate of reintervention.

2) **Toor 2012**, systematic review and meta-analysis of complications of UAE
   a. N=54 studies, 8159 patients
   b. Major complications 2.9%
      i. Hysterectomy 0.7%
      ii. Readmission 2.7%
      iii. DVT/PE 0.2%
3) **Beinfeld 2004**, cost effectiveness model
   a. UAE was more effective (8.29 vs 9.18 QALYs) and less expensive ($6,916 vs $7,847) than hysterectomy
4) **You 2012**, cost-effectiveness study
   a. Compared UAE to hysterectomy and myomectomy
   b. Over 5 yrs, total costs were $8,847 with UAE, $9,036 with myomectomy, and $8,418 with hysterectomy. QALYs were 4.245 with UAE, 4.273 with myomectomy, and 4.368 with hysterectomy
   c. Hysterectomy was found to be the most cost-effective treatment

<u>Other policies</u>

1) **Aetna 2012**
   a. Aetna considers transcatheter uterine artery embolization (UAE) medically necessary as an alternative to hysterectomy or myomectomy for the treatment of uterine fibroids when the member has persistence of one or more symptoms directly attributed to uterine fibroids (i.e., excessive menstrual bleeding (menorrhagia), bulk-related pelvic pain, pressure or discomfort, urinary symptoms referable to compression of the ureter or bladder, and/or dyspareunia).
2) **Cigna 2011**
   a. CIGNA covers uterine artery embolization (UAE) as medically necessary for the treatment of non-pedunculated uterine leiomyomas when ALL of the following criteria are met:
      i. The individual is experiencing symptoms that are directly attributable to uterine fibroids (e.g., bulk pressure or pelvic pain, profuse menstrual bleeding or anemia, dyspareunia, urinary problems caused by pressure on the urethra or bladder).
      ii. Conservative medical management has failed to control the symptoms being experienced.
      iii. Traditional surgical evaluation deems that the individual is a candidate for UAE and hysterectomy.
3) **Wellmark BCBS 2012**

a. Transcatheter embolization of uterine arteries as a treatment of uterine fibroids or as a treatment of postpartum uterine hemorrhage may be considered medically necessary**.**
b. One repeat transcatheter embolization of uterine arteries to treat persistent symptoms of uterine fibroids after an initial uterine artery embolization may be considered medically necessary.

Summary: UAE appears to be as efficacious as hysterectomy or myomectomy for treatment of uterine fibroids. The cost appears to be similar between these modalities when all costs (complications, hospitalization, etc.) are included.

Recommendations:

1) Add 37210 (Uterine fibroid embolization) to line 428 UTERINE LEIOMYOMA.
2) Change the treatment description of line 428 from TOTAL HYSTERECTOMY OR MYOMECTOMY to SURGICAL TREATMENT
3) Adopt the following changes to Guideline Note 40

GUIDELINE NOTE 40, UTERINE LEIOMYOMA
Line 428
Hysterectomy, myomectomy, or uterine artery embolization for leiomyomata may be indicated when all of the following are documented (A-D):

A) One of the following (1 or 2):
1) Patient history of 2 out of 3 of the following (a, b and c):
a. Leiomyomata enlarging the uterus to a size of 12 weeks or greater gestation
b. Pelvic discomfort cause by myomata (i or ii or iii):
i) Chronic lower abdominal, pelvic or low backpressure
ii) Bladder dysfunction not due to urinary tract disorder or disease
iii) Rectal pressure and bowel dysfunction not related to bowel disorder or disease
c. Rapid enlargement causing concern for sarcomatous changes of malignancy
2) Leiomyomata as probable cause of excessive uterine bleeding evidenced by (a, b, and c):
a. Profuse bleeding lasting more than 7 days or repetitive periods at less than 21-day intervals
b. Anemia due to acute or chronic blood loss (hemoglobin less than 10)
c. Documentation of mass by sonography
B) Nonmalignant cervical cytology, if cervix is present

C) Assessment for absence of endometrial malignancy in the presence of abnormal bleeding
D) Negative preoperative pregnancy test result unless patient is postmenopausal or has been previously sterilized

Ariel Smits:

Enclosed is UAE evidence for review.

Thank you,

Dr. Mary Costantino's office

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[Intervention Review]

Uterine artery embolization for symptomatic uterine fibroids

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ABSTRACT

Background

Uterine fibroids cause heavy prolonged bleeding, pain, pressure symptoms and subfertility. The traditional method of treatment has been surgery as medical therapies have not proven effective. Uterine artery embolization (UAE) has been reported to be an effective and safe alternative to treat fibroids in women not desiring future fertility. There is a significant body of evidence based on case controlled studies and case reports. This is an update of the review previously published in 2006.

Objectives

To review the benefits and risks of uterine artery embolization (UAE) versus other medical or surgical interventions for symptomatic uterine fibroids.

Search methods

We searched the Cochrane Menstrual Disorders & Subfertility Group Trials register (searched November 2011), the Cochrane Central Register of Controlled Trials (CENTRAL) in *The Cochrane Library*, 4th Quarter 2011), MEDLINE (1950 to November 2011) and EMBASE (January 1980 to November 2011). We also contacted authors of eligible RCTs for unpublished data.

Selection criteria

Randomised controlled trials (RCTs) of UAE versus any medical or surgical therapy for symptomatic uterine fibroids.

Data collection and analysis

Two of the authors (AS and JKG) assessed the trials and extracted the data independently.

Main results

Six RCTs with 732 women were included in this review. Three trials compared UAE with abdominal hysterectomy, two trials compared UAE with myomectomy and one trial compared UAE with surgery (43 hysterectomies and 8 myomectomies).

There was moderately good evidence that there is no significant difference between UAE and surgery in patient satisfaction rates at two years (OR 0.69, 0.40 to 1.21, 516 women, 5 trials) or at five years (OR 0.90, 95% CI 0.45 to 1.80, 295 women, 2 trials), and there was very low level evidence suggesting that quality of life at one year improved equally in both groups (mean difference -7.60,

Issue date: November 2010

NHS
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Uterine artery embolisation for fibroids

This document replaces previous guidance on uterine artery embolisation for the treatment of fibroids (interventional procedure guidance 94).

1 Guidance

1.1 Current evidence on uterine artery embolisation (UAE) for fibroids shows that the procedure is efficacious for symptom relief in the short and medium term for a substantial proportion of patients. There are no major safety concerns. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance and audit.

1.2 During the consent process patients should be informed, in particular, that symptom relief may not be achieved in some women, that symptoms may return and that further procedures may therefore be required. Patients contemplating pregnancy should be informed that the effects of the procedure on fertility and on pregnancy are uncertain.

1.3 Patient selection should be carried out by a multidisciplinary team, including a gynaecologist and an interventional radiologist.

1.4 NICE encourages further research into the effects of UAE compared with other procedures to treat fibroids, particularly for women wishing to maintain or improve their fertility.

2 The procedure

2.1 Indications and current treatments

2.1.1 Uterine fibroids, also known as uterine leiomyomas or uterine myomas, are benign tumours of smooth muscle cells and fibrous tissue that develop within the wall of the uterus. They are classified by their location relative to the layers of the uterus (subserous, intramural or submucous) and can be single or multiple.

2.1.2 Uterine fibroids are one of the most common gynaecological problems among women in the UK. They may be asymptomatic or may cause symptoms such as abnormal uterine bleeding, urinary incontinence, a feeling of pelvic pressure, or pain. They may also be associated with reproductive problems such as infertility and miscarriage.

2.1.3 Asymptomatic fibroids require no treatment. Treatments for symptomatic fibroids include hysterectomy and myomectomy.

2.2 Outline of the procedure

2.2.1 The aim of UAE for fibroids is to offer a less invasive alternative to hysterectomy or myomectomy with preservation of the uterus, and a faster recovery time. Uterine artery embolisation is sometimes used before a planned myomectomy.

2.2.2 With the patient under conscious sedation and local anaesthesia, a catheter is inserted into the femoral artery (bilateral catheters are sometimes used). Fluoroscopic guidance is used to manipulate the catheter into the uterine artery. Small embolisation particles are injected through the catheter into the arteries supplying the fibroids, with the aim of causing thrombosis and consequent fibroid infarction.

2.2.3 Various embolisation agents can be used for this procedure.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview, available at **www.nice.org.uk/guidance/IP/20/overview**

Interventional procedure guidance 367

This guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

This guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by NHS QIS for implementation by NHSScotland.

NHS Quality Improvement Scotland

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2.3 Efficacy

2.3.1 A register of 1387 patients reported that 84% and 83% of patients had an improvement in their symptoms after UAE at 6 and 24 months respectively. The register of 1387 patients reported an improvement in mean health-related quality of life scores (on a scale from 0 to 100) from 44.1 at baseline to 79.5 after UAE at a maximum 3-year follow-up ($p < 0.001$).

2.3.2 In a register of 2112 patients, the mean symptom score (on a scale from 0 to 100) improved from 58.6 at baseline to 16.5 among 1218 patients at 3-year follow-up ($p < 0.001$).

2.3.3 A randomised controlled trial (RCT) of 157 patients treated by UAE or surgery (hysterectomy or myomectomy) reported symptom improvement in both groups, but this improvement was significantly greater among patients treated by surgery than by UAE ($p = 0.004$ at 1 month, $p = 0.03$ at 12 months).

2.3.4 The register of 1387 patients reported a mean uterine volume reduction of 40% ($n = 666$) and a mean reduction in fibroid diameter of 2.2 cm ($n = 847$).

2.3.5 The register of 2112 patients reported a re-intervention rate of 15% during a 3-year follow-up (10% hysterectomy, 3% myomectomy and 2% repeat UAE).

2.3.6 An RCT of 177 patients treated by UAE or hysterectomy reported that 28% (23/81) of UAE-treated patients had required hysterectomy at 5-year follow-up.

2.3.7 An RCT of 121 women treated by UAE or myomectomy reported that 50% (13/26) of women who tried to conceive after UAE became pregnant compared with 78% (31/40) of women after myomectomy at a mean follow-up of 25 months ($p < 0.05$). The rate of spontaneous abortion or missed miscarriage was 64% in the UAE group and 23% in the myomectomy group ($p < 0.05$).

2.3.8 The Specialist Advisers listed key efficacy outcomes as symptom improvement, quality of life and the need for further treatment.

2.4 Safety

2.4.1 Uterine infection was reported in 2% (28/1387) of patients in one of the registers (there were significantly fewer infective complications after discharge in patients who received prophylactic antibiotics compared with those who did not; figures not provided). Septic shock and multiple organ failure leading to death 25 days after UAE occurred in 1 patient in a case series of 21 patients, reported in a systematic review of 36 papers. Septicaemia and emergency myomectomy or hysterectomy were reported in 3% (17/649) of UAE-treated patients in a non-randomised comparative study of 1108 patients.

2.4.2 Arterial dissection or perforation were reported in 2 patients, groin bleeding or pseudoaneurysm were reported in 2 patients, and femoral artery occlusion was reported in 1 patient from the register of 1387 patients (events reported prior to discharge from hospital; clinical sequelae not described).

2.4.3 One case of bowel perforation treated by laparotomy was reported in the register of 1387 patients.

2.4.4 A severe vasovagal event requiring atropine was reported in 1 out of 106 UAE-treated patients in the RCT of 157 patients.

2.4.5 The Specialist Advisers listed adverse events reported in the literature as uterine infarction, bladder and vulval damage, ovarian damage, post-embolisation syndrome, pain, vaginal discharge and premature menopause.

3 Further information

3.1 For related NICE guidance see **www.nice.org.uk**

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See **www.nice.org.uk/guidance/IPG367/publicinfo**

Ordering printed copies
Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N2359 for this guidance or N2360 for the 'Understanding NICE guidance'.

National Institute for Health and Clinical Excellence
MidCity Place, 71 High Holborn, London WC1V 6NA; **www.nice.org.uk**

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Randomised comparison of uterine artery embolisation (UAE) with surgical treatment in patients with symptomatic uterine fibroids (REST trial): 5-year results

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Objective To compare the long-term results of uterine artery embolisation (UAE) with surgery for women with symptomatic uterine fibroids.

Design Pragmatic, open, multicentre, randomised trial.

Setting Twenty-seven participating UK secondary care centres.

Sample Women aged ≥18 years with symptomatic fibroids who were considered to justify surgical treatment.

Methods In total, 157 women were randomised (in a 2:1 ratio): 106 to UAE and 51 to surgery (hysterectomy 42; myomectomy nine).

Main outcome measures Quality of life at 5 years, as assessed by the Short Form General Health Survey (SF-36). Secondary measures included complications, adverse events and the need for further intervention.

Results There were no significant differences between groups in any of the eight components of the SF-36 scores at 5 years (minimum $P = 0.45$). Symptom score reduction and patient satisfaction with either treatment was very high, with no group difference. Rates of adverse events were similar in both groups (19% embolization and 25% surgery; $P = 0.40$). The 5-year intervention rate for treatment failure or complications was 32% (UAE arm) and 4% (surgery arm), respectively. The initial cost benefit of UAE over surgery at 12 months was substantially reduced because of subsequent interventions, with treatments being cost neutral at 5 years.

Conclusions We have found that UAE is a satisfactory alternative to surgery for fibroids. The less invasive nature of UAE needs to be balanced against the need for re-intervention in almost a third of patients. The choice should lie with the informed patient.

Keywords Embolisation, fibroids, leiomyoma.

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Introduction

Uterine fibroids are a common health problem in pre-menopausal women, and treatment is traditionally surgical (hysterectomy or myomectomy). Since its inception in 1995,[1] uterine artery embolization (UAE) has become a well-established alternative treatment for those wishing to avoid surgery and preserve their uterus. The American College of Obstetrics and Gynecology, the Royal College of Obstetricians and Gynaecologists (UK) and the National Institute for Health and Clinical Excellence (NICE) (UK) have all endorsed its safety and short-term efficacy, with the caveat that data regarding the long-term outcomes are required.

The randomised trials comparing UAE with surgery have all reported short-term outcomes,[2–5] but long-term clinical data have only recently been published.

The aim of this study is to provide 5-year clinical and economic outcomes of the REST trial cohort (UAE versus

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Uterine Artery Embolization versus Myomectomy: Impact on Quality of Life—Results of the FUME (Fibroids of the Uterus: Myomectomy versus Embolization) Trial

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Abstract

Purpose This study was designed to compare quality of life (QoL) outcomes after uterine artery embolization (UAE) or myomectomy.

Methods Women with symptomatic fibroids diagnosed by ultrasound who wished to preserve their uterus were randomized to myomectomy ($n = 81$) or UAE ($n = 82$). Endpoints at 1 year were QoL measured by a validated questionnaire, hospital stay, rates of complications, and need for reintervention.

Results UAE patients had shorter hospitalization (2 vs. 6 days, $p < 0.001$). By 1 year postintervention, significant and equal improvements in QoL scores had occurred in both groups (myomectomy $n = 59$; UAE $n = 61$). There had been two (2.9%) major complications among UAE versus 6 (8%) among myomectomy patients (not significant). By 2 years, among UAE patients ($n = 57$) there were eight (14.0%) reinterventions for inadequate symptom control compared with one (2.7%) among myomectomy patients ($n = 37$). Half of the women who required hysterectomy had concomitant adenomyosis missed by US.

Conclusions UAE and myomectomy both result in significant and equal improvements in QoL. UAE allows a shorter hospital stay and fewer major complications but with a higher rate of reintervention.

Keywords Fibroid · Myomectomy · Quality of life · Uterine artery embolization

Introduction

A woman with symptomatic fibroids seeking treatment and wishing to preserve her uterus currently has the options of myomectomy [1] or the radiological therapies, uterine artery embolization (UAE) or high-intensity focussed ultrasound (HIFU) [2]. The number of such women is increasing because fibroids are most symptomatic in the 30–40-year age group, and women are starting their families in their 30 s or later [3]. Hysterectomy is regarded as too radical by many patients, regardless of fertility concerns. Therefore, myomectomy often is offered if fertility retention is explicitly sought, but UAE is less invasive, cheaper, and associated with a shorter hospital stay and a quicker recovery [2]. UAE could be an attractive alternative to myomectomy if robust data on quality of life and some comparable information on subsequent fertility were available. However, there are very little data that allow an evidence-based choice between the two. Myomectomy is the time-honored conventional treatment of proven efficacy with regard to symptom relief [4] and improved fertility outcome [5], but it is associated with significant morbidity, especially excessive operative blood loss, adhesion formation, and recurrence of fibroids, all of which might compromise the fertility potential for which it often is performed [6–8]. UAE is now widely used, and its safety,

This study was approved by the Wandsworth Research Ethics committee (Ref 01.96.3).

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Complication Rates and Effectiveness of Uterine Artery Embolization in the Treatment of Symptomatic Leiomyomas: A Systematic Review and Meta-Analysis

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Pasteur Rasuli

OBJECTIVE. The purpose of this meta-analysis was to determine the rates of major complications, other associated adverse events, reintervention, and clinical improvement from studies reporting complications of uterine artery embolization (UAE) for the treatment of symptomatic leiomyomas.

MATERIALS AND METHODS. PubMed, Medline, Embase, and Cochrane databases were searched for publications on the treatment of leiomyomas by UAE. Data pertaining to study characteristics, numbers of complications, symptomatic improvement, and reinterventions were collected by two readers. Pooled event rates were calculated using a random effects method.

RESULTS. Fifty-four study populations met the inclusion criteria, yielding a total of 8159 patients. There were no reported deaths. Major complications occurred at a rate of 2.9% (95% CI, 2.2–3.8%). The rate of hysterectomy for resolution of a complication from UAE was 0.7% (0.5–0.9%), and the rate of readmission was 2.7% (1.9–3.7%). Multiple other specific complications were recorded including leiomyoma tissue passage (4.7% [3.9–5.7%]), deep venous thrombosis or pulmonary embolism (0.2% [0.2–0.4%]), and permanent amenorrhea (3.9% [2.7–5.3%]). Reintervention rates including repeat UAE, myomectomy, or hysterectomy calculated per patient-year occurred at 5.3% (4.2–6.4%) with follow-up ranging from 0.25 to 5 years. Clinical symptomatic improvement ranged from 78% to 90%, with follow-up ranging from 0.25 to 2 years.

CONCLUSION. Symptomatic uterine leiomyoma treatment by UAE is an effective procedure with a low rate of major complications supporting its use as an alternative to hysterectomy.

Keywords: complications, leiomyoma, meta-analysis, uterine artery embolization

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0361–803X/12/1995–1153

Leiomyomas are the most common pelvic tumors in women [1]. Although many are asymptomatic, leiomyomas may cause significant morbidity requiring medical attention. Since the first report from Ravina et al. [2] in 1995, uterine artery embolization (UAE) has emerged as an effective noninvasive treatment option for women with symptomatic leiomyomas [3]. UAE is considered a safer procedure with fewer major complications when compared with hysterectomy; however, UAE has led to a greater number of reinterventions [4–6].

A broad range of complications have been described after UAE with widely varying rates. Even though it is an extremely uncommon outcome, there have been case reports of death as a result of a complication after UAE [7–11]. Major complication rates have been reported ranging from 1% to 17% [12–14]. Thus, the true rates of complications that might be expected are not known.

A meta-analysis of the published literature on UAE was undertaken with the intent of improving the understanding of this treatment and its associated complications. To our knowledge, there have been no previous comprehensive systematic reviews of UAE in the treatment of leiomyomas. The primary objective of this study was to use meta-analysis to determine the rates of major complications, subsequent hysterectomy for treatment of complications, and specific adverse events in women with symptomatic leiomyomas being treated by UAE. As a secondary objective, we sought to determine the rates of symptom improvement and reintervention after UAE.

Materials and Methods

This meta-analysis was performed according to the standards from Meta-analysis of Observational Studies in Epidemiology [15] and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA statement) [16]. The protocol of this study has not been published elsewhere.

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Cost-Effectiveness of Uterine Artery Embolization and Hysterectomy for Uterine Fibroids

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Abstract

PURPOSE: To compare the cost–effectiveness of uterine artery embolization (UAE) with that of hysterectomy for women with symptomatic uterine fibroids.

MATERIALS AND METHODS: The authors developed a decision model to compare the costs and effectiveness of UAE and hysterectomy. In the model, a cohort of women aged 40 years with a diagnosis of uterine fibroids and no desire for future pregnancy was followed up until menopause. The analysis was performed from a societal perspective, including all costs and effects, regardless of who incurs them. Transition probability and quality-of-life estimates were obtained from the literature and a gynecologist, whereas costs (in 1999 U.S. dollars) were estimated by using rates of Medicare reimbursement for hospital costs and physician fees. Sensitivity analyses of key estimates were performed. Results were expressed in costs per quality-adjusted life-year (QALY).

RESULTS: UAE was more effective (8.29 vs 8.18 QALYs) and less expensive ($6,916 vs $7,847) than hysterectomy. Cost–effectiveness results, with the exception of quality-of-life data, were robust to changes in most model assumptions. When the quality-of-life adjustment was eliminated, the two procedures were equally effective.

CONCLUSION: UAE is a cost–effective alternative to hysterectomy across a wide range of assumptions about the costs and effectiveness of the two procedures. However, the study results were sensitive to changes in quality-of-life values.

Uterine fibroids, or leiomyomata uteri, are caused by abnormal growth of sex steroid–responsive muscle cells in the myometrium. Although benign, fibroids can grow at very rapid rates and cause a constellation of symptoms, including menorrhagia (excessive menstrual bleeding), pelvic pain, pelvic pressure, infertility, pregnancy loss, and abdominal distention (1). As a result, some women may find their ability to work, participate in leisurely activities, and/or enjoy a quality of life comparable to that of women without fibroids hindered by fibroid-induced symptoms.

Symptomatic fibroids have generally been treated with hysterectomy. This common surgery is invasive, however: Complications occur with approximately 10%–15% of surgeries, and several days of hospital stay and a recovery time of about 6 weeks can be expected (2,3). In 1998, approximately 645,000 hysterectomies were performed in the United States, making this surgery second to only cesarean section as the most common gynecologic surgical procedure (4). More than one-third of hysterectomies are performed for the treatment of uterine fibroids, making these tumors the largest single indication for the surgery (5).

Centre for Reviews and Dissemination

NHS National Institute for Health Research

Uterine artery embolization, hysterectomy, or myomectomy for symptomatic uterine fibroids: a cost-utility analysis

You JH, Sahota DS, Yuen PM

CRD summary
This study assessed the comparative cost-effectiveness of hysterectomy, myomectomy, and uterine artery embolisation for the treatment of patients with symptomatic uterine fibroids. The authors concluded that hysterectomy was the most cost-effective treatment as it was both more effective and less expensive than the other procedures, for patients who did not have a preference for uterus-conserving interventions. The analysis was based on a valid approach and was well presented. The authors' conclusions appear to be valid.

Type of economic evaluation
Cost-utility analysis

Study objective
This study assessed the comparative cost-effectiveness of hysterectomy, myomectomy, and uterine artery embolisation (UAE) for the treatment of adult women with symptomatic uterine fibroids.

Interventions
Two surgical procedures, which were hysterectomy and myomectomy, were compared with one non-surgical option, which was UAE.

Location/setting
Hong Kong/hospital.

Methods

Analytical approach:
The analysis was based on a Markov model with a five-year time horizon. The authors stated that the perspective society was adopted.

Effectiveness data:
The clinical evidence was identified through a systematic search of the MEDLINE database and it included randomised controlled trials (RCTs) or meta-analyses of RCTs that compared at least two of the three options being evaluated. The rate of procedural success was the key clinical input and was taken from four RCTs. The details of how multiple estimates, where available, for a single input were combined were not reported.

Monetary benefit and utility valuations:
The utility valuations were derived from a study of interviews with patients with menorrhagia. Some assumptions were made for the utility values associated with other conditions.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure and were discounted at an annual rate of 4%.

Cost data:
The economic analysis included three main cost categories: the initial intervention (procedure, hospitalisation, treatment of complications, salvage procedure for failed interventions, readmissions, and out-patient follow-up), re-intervention for symptomatic relapses or persistence (items as for initial intervention), and the indirect costs of productivity lost, which were calculated using the human capital approach. Average wages in the Hong Kong population were used. Medical costs were based on official prices from the Hong Kong Gazette. All costs were presented in US dollars ($) and future costs were discounted at an annual rate of 4%.

Analysis of uncertainty:
A deterministic one-way sensitivity analysis was undertaken on all the inputs, using published or assumed ranges of values. A probabilistic sensitivity analysis was also undertaken to consider the simultaneous variability of the model inputs, using a Monte Carlo simulation with triangular distributions for the inputs.

Results
Over five years, the total costs were $8,847 with UAE, $9,036 with myomectomy, and $8,418 with hysterectomy. The QALYs were 4.245 with UAE, 4.273 with myomectomy, and 4.368 with hysterectomy. Hysterectomy was the dominant strategy as it was less expensive and more effective than the other interventions. The incremental cost per QALY gained with myomectomy over UAE was $6,750.

Hysterectomy became the dominant strategy after three years, while at one-year follow-up UAE was less costly and more effective. This was due to the lower rate of re-intervention over time associated with hysterectomy.

The deterministic analysis showed that the total costs were sensitive to variations in the rate of re-intervention in the myomectomy group, the relative cost of UAE compared with hysterectomy, and the cost of procedure and duration of hospitalisation in both the hysterectomy and myomectomy groups, but the findings were robust. The probabilistic analysis also showed that hysterectomy was the most effective option in more than 97% of cases and the least expensive option in almost 80% of cases.

Authors' conclusions
The authors concluded that hysterectomy was the most cost-effective treatment, as it was both more effective and less expensive than the other available procedures, for patients who did not have a preference for uterus-conserving interventions.

CRD commentary

Interventions:
The authors justified their selection of the comparators: hysterectomy and myomectomy were two conventional surgical procedures for treatment of symptomatic uterine fibroids, while UAE was a non-surgical alternative, which might be preferred when the avoidance of surgery or the conservation of the uterus were desired.

Effectiveness/benefits:
The clinical analysis was based on a valid approach that ensured the identification of the most relevant sources of data. The details of the literature review were reported and the inclusion of high-quality studies (RCTs and meta-analyses) enhances the validity of the clinical estimates. The authors appear to have used their own judgement to select the most appropriate estimate from the identified evidence. QALYs are an appropriate benefit measure for this patient population, given the impact of the disease on the quality of life. Almost all the utility values were based on authors' assumptions rather than on peer-reviewed literature, but changes in these inputs did not substantially alter the results.

Costs:
The analysis of costs adopted a broad perspective and included all the relevant categories. The costs were often presented as macro-categories and a detailed description of the unit costs and quantities of resources was not provided. This reduces the transparency of the economic analysis. Similarly, the price year was not reported, which limits the possibility of making reflation exercises in other time periods. The sources of data were reported and reflected the authors' setting.

Analysis and results:
The costs and benefits were appropriately reported and cost-utility ratios were calculated, when required. The issue of uncertainty was satisfactorily investigated using appropriate approaches and the results were clearly presented and discussed. The authors justified their use of a Markov model on the grounds of the recurrent nature of the disease. They also stated that a longer time horizon would have introduced further uncertainty into the analysis. The model findings were validated using recent data. The authors stated that a potential limitation of their analysis was that most of the estimates had to be taken from studies conducted outside Hong Kong.

Concluding remarks:
The analysis was based on a valid approach and was well presented. The authors' conclusions appear to be valid.

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Clinical Policy Bulletin:
Fibroid Treatment
Number: 0304

Policy History
Last Review: 10/05/2012
Effective: 10/13/1998
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Review History
Definitions
Additional Information
Clinical Policy Bulletin Notes

Policy

1. Aetna considers transcatheter uterine artery embolization (UAE) medically necessary as an alternative to hysterectomy or myomectomy for the treatment of uterine fibroids when the member has persistence of one or more symptoms directly attributed to uterine fibroids (i.e., excessive menstrual bleeding (menorrhagia), bulk-related pelvic pain, pressure or discomfort, urinary symptoms referable to compression of the ureter or bladder, and/or dyspareunia).

   Aetna considers other uses of transcatheter UAE experimental and investigational because its effectiveness for indications other than the one lised above has not been established.

2. Aetna considers the following treatments for uterine fibroids experimental and investigational because their safety and effectiveness have not been established:

   - Acupuncture
   - Cryomyolysis
   - Laparoscopic uterine artery occlusion
   - MRI-guided ultrasound (focused ultrasound) ablation.

Background

Uterine fibroids (leiomyomata) represent the most common gynecological tumor in women of reproductive age and are responsible for over 200,000 hysterectomies per year. They can cause a variety of symptoms including menometrorrhagia, dysmenorrhea, pelvic pain, reproductive failure, and compression of adjacent pelvic viscera, or be totally asymptomatic. A large array of treatment options exist for this disorder. Surgical treatments include hysterectomy, abdominal myomectomy, laparoscopic myomectomy, myolysis, and more recently MRI-guided ultrasound ablation. Non-surgical treatments include medical therapy (e.g., gonadotropin-releasing hormone agonist) and uterine artery

CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Effective Date 1/15/2011
Next Review Date 1/15/2013
Coverage Policy Number 0018

Subject **Uterine Artery Embolization**

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Hyperlink to Related Coverage Policies

Endometrial Ablation
Hysterectomy
Magnetic Resonance- (MR) Guided Thermal Ablation of Fibroids

INSTRUCTIONS FOR USE

*Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines.*

Coverage Policy

CIGNA covers uterine artery embolization (UAE) as medically necessary for the treatment of non-pedunculated uterine leiomyomas when ALL of the following criteria are met:

- The individual is experiencing symptoms that are directly attributable to uterine fibroids (e.g., bulk pressure or pelvic pain, profuse menstrual bleeding or anemia, dyspareunia, urinary problems caused by pressure on the urethra or bladder).
- Conservative medical management has failed to control the symptoms being experienced.
- Traditional surgical evaluation deems that the individual is a candidate for UAE and hysterectomy.

CIGNA does not cover UAE in any of the following clinical situations because its use is considered experimental, investigational or unproven (this list may not be all-inclusive):

- when causes of abnormal uterine bleeding other than from a fibroid have not been sufficiently excluded
- in women with gynecologic or bladder malignancy, undiagnosed/untreated anemia, bleeding disorder, chronic pelvic inflammatory disease (PID) or other active genito-urinary infection, diabetes, vasculitis, or prior pelvic irradiation
- in women requiring surgery for associated gynecological conditions, such as pedunculated leiomyomas, other lesions, adnexal disease, uterine prolapse or stress incontinence

General Background

Occlusion of Uterine Arteries Using Transcatheter Embolization

Medical Policy: 04.01.07
Original Effective Date: February 1999
Reviewed: September 2012
Revised: September 2012

Contact Information

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:
Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
P.O. Box 9232
Des Moines, IA 50306-9232

Benefit Application
Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged or new medical literature may have been published. This Medical Policy will be reviewed regularly and be updated as scientific and medical literature becomes available.

Description:

Transcatheter uterine artery embolization (UAE) is a minimally invasive technique that involves the injection of small particles into the uterine arteries to block the blood supply to the uterus and uterine fibroids. It potentially serves as an alternative to hysterectomy. UAE has also been used to treat other conditions including postpartum hemorrhage (PPH) and cervical ectopic pregnancy.

Uterine leiomyomata (i.e., fibroids) are extremely common benign tumors that can be located primarily within the uterine cavity (submucosal fibroids) or on the serosal surface of the uterus. Treatment for uterine fibroids is usually sought when they are associated with menorrhagia, pelvic pain, urinary symptoms (i.e., frequency), or are suspected to be the cause of infertility. Treatment options include medical therapy with gonadotropin agonists or gestagen suppression or various types of surgical therapy. Hysterectomy is considered the definitive surgical treatment for those who no longer wish to maintain fertility. Various types of myomectomy, which describes removal of the fibroid with retention of the uterus, have also been described. Hysteroscopic myomectomy involves removal of submucosal fibroids using either a resectoscope or a laser. Subserosal fibroids can be removed via an open abdominal or laparoscopic approach. Laparoscopic laser coagulation of uterine fibroids is a unique approach in that the fibroid is not physically removed, but instead multiple (up to 75) laparoscopic laser punctures of the uterine fibroids are performed in an effort to devascularize the fibroid and

Therapeutic Activities

Question: Should CPT 97530 (Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes) be added to additional lines on the Prioritized List?

Question source: Annette Broddie, OT

Issue: 97530 is currently on about 50 lines on the Prioritized List. Ms. Broddie has contacted the HERC about adding this code to several additional lines. Specifically, Ms. Broddie has suggested adding 97530 to lines 37 SEVERE BIRTH TRAUMA FOR BABY and 133 ATTENTION DEFICIT DISORDERS WITH HYPERACTIVITY OR UNDIFFERENTIATED. Additionally, Ms. Broddie recommended adding the basic PT/OT evaluation and treatment codes (CPT 97001-4) to line 133. Note: line 133 treatment description is "Medical/psychotherapy."

Specific comments from Ms. Broddie

1) Adding PT/OT CPT codes to line 37
    a. Line 37 severe birth trauma of baby: OT and PT can evaluate when look at the line 37 specifically although it is not listed on OT/PT treatment code list on OHP/DMAP web as covered line (I believe). Any suggestions? BABY can not be treated with 97530 (most appropriate code) and I did not see any specific feeding code. BABY can be treated with 97116 Gait training (includes stair climbing), 97110 therapeutic exercise, 97113 aquatic therapy, AND 97150 group therapy! Really?
    b. Note: the PT/OT evaluation and re-evaluation CPT codes (97001-4) are included on this line. PT/OT treatment codes such as 97110-6, 97124, 97140, and 97150 are included on this line.
2) Adding PT/OT CPT codes to line 133
    a. If your child was hyperactive and unsafe would you seek treatment by a counselor? Dietician? Medicate with drugs (many that have no long term studies on the effects)? or an OT that can actually help change the body's neurological system processing by working on the vestibular system, touch system, auditory system, visual system, reflexes, and other underlying causes for the behavior without medication? Please specify the specific codes would you use that would pair with the appropriate treatment code of 97530?
    b. Note: the HSC reviewed therapies for ADHD recently, and did not find evidence for use of occupational therapy or physical therapy for treatment of this condition

Therapeutic Activities

Recommendations:

1) Add 97530 to line 37 SEVERE BIRTH TRAUMA FOR BABY and to line 318 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
2) Add line 37 to the PT/OT guideline (Guideline note 6)
    a. Has all PT/OT evaluation and treatment codes but is not currently included in the guideline
3) Do not add PT/OT service codes to line 133 ATTENTION DEFICIT DISORDERS WITH HYPERACTIVITY OR UNDIFFERENTIATED as no evidence found in recent review for use of PT/OT services for this condition

Section 6

Previously Discussed Items Part 2

Menstrual Bleeding Disorders

Question: Should guideline note 44, menstrual bleeding disorders, be modified?

Question source: DMAP

Issue:
At the December, 2012 VbBS meeting, the subcommittee heard concerns a from DMAP about the Hysterectomy Guideline Note 44 for menstrual bleeding disorders. DMAP is concerned that the requirement for having a documented hemoglobin of less than 10. DMAP approves several cases a month in which all criteria are met except the hemoglobin level. DMAP requested that VbBS/HERC consider removing this requirement.

At the December meeting, the discussion was mainly around concerns that without the documented hemoglobin level, there would be no way to determine if anemia was present. Removal of this requirement would allow more cases and therefore increase costs. HERC staff was asked to present this to the OHP Medical Directors and obtain feedback on how the plans are using this guideline.

The OHP Medical Directors indicated that nearly all the plans are using the 10mg/dl as a firm cutoff and several argued that this is the only objective useful cutoff. There were major concerns with eliminating it altogether, with concerns this would increase hysterectomies dramatically. There were concerns that opening the door was also an inappropriate use of funds because many of these women are perimenopausal and their symptoms will cease. If it is felt to be overly strict, a proposal that was made to have the same language, plus potentially a lower to 11mg/dl while on iron therapy. All in all, largely there is a lot of support for the guideline as it stands, but with potential willingness to have a lower threshold for those on iron therapy, acknowledging it may be hard for women to fall below 10 prior to physician‟s initiating iron treatment.

DMAP feels that the existing guideline is too cumbersome and results in too many manual reviews. Wally Shaffer, DMAP medical director suggests increasing the cut off to 11 g/dL or otherwise allowing alternative definitions of anemia.

All sources agree that a very specific definition of anemia is useful and should be maintained in the guideline.

HERC staff were also directed to search for other insurer criteria for hysterectomy for abnormal uterine bleeding to give context to the HERC guideline. The following policies were found

1) **NICE 2007**
    a. For clinical purposes, heavy menstrual bleeding (HMB) should be defined as excessive menstrual blood loss which interferes with the woman‟s physical, emotional, social and material quality of life, and which can occur alone or in combination with other symptoms.
    b. Hysterectomy should not be used as a first-line treatment solely for HMB. Hysterectomy should be considered only when:

i. other treatment options have failed, are contraindicated or are declined by the woman
ii. there is a wish for amenorrhoea
iii. the woman (who has been fully informed) requests it
iv. the woman no longer wishes to retain her uterus and fertility.

c. Measuring menstrual blood loss either directly (alkaline haematin) or indirectly („pictorial blood loss assessment chart") is not routinely recommended for HMB. Whether menstrual blood loss is a problem should be determined not by measuring blood loss but by the woman herself.

2) RAND 1997

a. Anemia is defined as a hematocrit<30% or hemoglobin<10 g/dl or a drop in hemotocrit of ≥ 6% or drop in hemoglobin of ≥ 2 g/dL in the past 6 months AND the woman has received treatment with iron for 3 months or blood transfusions
b. Premenopausal women with abnormal uterine bleeding of unknown etiology may be candidates for hysterectomy if the bleeding is a continuing problem that results in significant anemia or major impairment and is not controlled by hormone therapy
c. For women who are not anemic and are without major impairment, hysterectomy for abnormal uterine bleeding of unknown etiology is not appropriate

3) Cigna 2012

a. Hysterectomy is covered for abnormal (premenopausal) uterine bleeding with **ALL** of the following:
i. bleeding is recurrent (i.e., lasting longer than seven days or repetitive periods at less than 21-day intervals) and unresponsive to medical management, including at least a three-month trial of hormonal manipulation unless contraindicated or not tolerated
ii. no evidence of other remediable pathology on diagnostic evaluation of the endometrium completed within the last 24 months by endometrial biopsy or D&C
iii. no evidence of other remediable pathology on diagnostic imaging of uterine cavity by US, sonohysterogram, hysteroscopy, hysterosalpingogram
iv. alternative therapeutic approaches (e.g., endometrial ablation) have been given careful consideration

Recommendation:

1) Allow slightly broader definition of anemia in Guideline Note 44. Several options are possible:
    a. Add a clause to A1b to allow for acute hemoglobin change to qualify as anemia even if it does not reach the 10 g/dL cut-off
        i. "(hemoglobin less than 10 g/dL or drop in hemoglobin of ≥ 2 g/dL in the past 6 months)"
        ii. Based on RAND review (1997)
    b. Change A1b to "hemoglobin less than 11 g/dL" or "hemoglobin less than 11 g/dL if use of iron is documented"
    c. Change A1b to "Anemia requiring iron therapy or blood transfusion"
        i. Will likely increase the number of qualifying patients considerably
    d. Change A1 (a and b) to "Heavy menstrual bleeding as defined as excessive menstrual blood loss which interferes with the woman's physical, emotional, social and material quality of life, and which can occur alone or in combination with other symptoms."
        i. Based on NICE guideline
        ii. Very general and open to interpretation
    e. DMAP recommended option
        i. Change A1b to "(hemoglobin less than 10 g/dL or hemoglobin less than 11 g/dL if use of iron is documented)" or similar
        ii. Add clause A1c to be required in addition to clause a and b: "Bleeding causes major impairment or interferes with quality of life"
2) Change the "and" on A1a to "or"
    a. Unlikely to have both long menses and closely spaced menses. One of these two situations is likely to result in anemia

GUIDELINE NOTE 44, MENSTRUAL BLEEDING DISORDERS

Line 446

Endometrial ablation or hysterectomy for abnormal uterine bleeding in premenopausal women may be indicated when all of the following are documented (A-C):

A) Patient history of (1, 2, 3, 4, and 5):

1) Excessive uterine bleeding evidence by (a and b):

a) Profuse bleeding lasting more than 7 days ~~and~~ **or** repetitive periods at less than 21-day intervals

b) Anemia due to acute or chronic blood loss (hemoglobin less than 10 g/dL) prior to iron therapy

2) Failure of hormonal treatment for a six-month trial period or contraindication to hormone use (oral contraceptive pills or patches, progesterone-containing IUDs, injectable hormone therapy, or similar)

3) No current medication use that may cause bleeding, or contraindication to stopping those medications
4) Endometrial sampling performed
5) No evidence of treatable intrauterine conditions or lesions by (a, b or c):
    a) Sonohysterography
    b) Hysteroscopy
    c) Hysterosalpingography

B) Negative preoperative pregnancy test result unless patient has been previously sterilized
C) Nonmalignant cervical cytology, if cervix is present

Heavy menstrual bleeding

National Collaborating Centre for Women's and Children's Health

Commissioned by the National Institute for Health and Clinical Excellence

January 2007

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1 Introduction

Heavy menstrual bleeding (HMB) has an adverse effect on the quality of life of many women. It is not a problem associated with significant mortality. Many women seek help from their general practitioners and it is a common reason for referral into secondary care.

In order for women to be treated successfully, it is essential that the underlying problem is understood by both the patient and the healthcare professional. This guideline provides background information as well as covering epidemiology, physiology, investigation and, ultimately, treatment. The aim is to consider the evidence and review it, taking into account both the woman's and the healthcare professional's viewpoints and interests. This is not always easy but it is anticipated that the information contained in the guideline will help women reach an informed and beneficial decision with their doctors. Once they have read the guideline, they will know what questions to ask and what the options available to them are. Constructive dialogue should allow patients to be able to trust the advice given by their practitioner as they will be confident that they have the latest information and will be able to use it to inform this decision-making process.

Clinical guidelines have been defined as systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions. This guideline has been developed with the aim of providing guidance on HMB. The effectiveness of the various treatments as well as their risks and benefits are discussed in relation to their use in the treatment of HMB but the discussion cannot be extrapolated to the use of particular treatments to relieve other symptoms, such as hysterectomy for cancer or endometriosis. The implications of each treatment in relation to fertility are also clearly stated so that no woman will undergo treatment that renders her infertile unless this is her specific wish.

Uterine fibroids are a common cause of HMB. The diagnosis and management are discussed in some depth although treatment for symptoms other than HMB is not included. The most up-to-date information is discussed so that the guideline will reflect current best practice. There are other gynaecological conditions such as adenomyosis or endometriosis where HMB may be associated with other menstrual symptoms as part of the presenting complaint. These conditions are excluded because HMB is not usually the principal presenting complaint and also because endometriosis could be the topic of a separate guideline.

In the early 1990s it was estimated that at least 60% of women presenting with HMB would have a hysterectomy to treat the problem, often as a first line. However, things have changed and the number of hysterectomies is decreasing rapidly. Hysterectomy is a major operation associated with significant complications in a minority of cases. It is also an emotive procedure: because the womb and fertility are often seen as being part of a woman's identity, the concept can be problematic and undesirable for some people. Nevertheless, clinically, hysterectomy is associated with a very high satisfaction rate by those who have undergone the operation. The high number of hysterectomies, the apparent lack of pathology and the lack of discussion of alternatives was a major cause for concern by professionals as well as the public. One of the principal aims of this guideline is to consider hysterectomy as well as the other treatment options and determine when they are likely to be the most appropriate for any particular individual.

Alternative effective treatments to hysterectomy are available for women with HMB, particularly for those who have a normal uterus and no significant pathology such as large uterine fibroids. As a result, the hysterectomies now performed tend to be more complicated than many of those in the past. This has significant implications for the acquisition and maintenance of surgical skills and this area is covered in some depth in this guideline. Surgical competence is an extremely important issue and recommendations are included as to how this might be made apparent to a patient. One possibility suggested is that details of the surgical practice of individual gynaecologists should be in the public domain.

It is often difficult for patients to appreciate that not all women are suitable for a particular new minimally invasive procedure. New therapies are often discussed in the media and this can give

Hysterectomy

Clinical Recommendations and Indications for Use

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PURPOSE AND SCOPE

These recommendations were developed as a research tool to provide an authoritative guide to assist physicians in deciding whether to recommend hysterectomy for non-emergency, non-malignant disease. *They apply only to that decisionmaking process and are not a suitable resource for overall management of women with the condition described.*

The recommendations assume that the reader is knowledgeable about the full spectrum of gynecological disease and its management, including indications for and interpretation of diagnostic tests, and is qualified to provide pre-, intra-, and post-operative care. The recommendations also assume that patient care will be provided in an institution that has the resources to provide high-quality care.

How the Recommendations Were Developed

These recommendations represent expert judgments about the appropriateness of hysterectomy for a large number of clinical scenarios. They were developed by a working group of obstetricians/gynecologists and are based on appropriateness ratings developed through the RAND appropriateness method. This expert group judgment process includes five steps:

1. **Literature review.** A comprehensive review of the literature was carried out of the indications for hysterectomy and the effectiveness and risks associated with alternative treatments for conditions that may be treated by hysterectomy. This literature review is contained in the companion document, *Hysterectomy: A Review of the Literature on Indications, Effectiveness, and Risks* (MR-592/2-AHCPR).

2. **Derivation of indications.** A set of indications was developed that reflects how clinicians think about hysterectomy. The objective was to include all likely clinical scenarios where hysterectomy might be recommended for non-emergency, non-malignant disease, and to incorporate all of the key variables that enter into the decisionmaking process. The resulting "indications" are highly detailed, individually unique, and mutually exclusive. A total of 2,332 potential indications for hysterectomy were developed.

3. **Selection of an expert panel.** A multidisciplinary panel of nine physicians was selected from individuals nominated by the relevant specialty societies as well-recognized experts and experienced clinicians. The composition of the panel is balanced three ways. It includes physicians who perform hysterectomy and those who refer women for surgery, academicians and those in private practice, and representatives from different geographical sections of the country. There were five obstetrician/gynecologists, two internists, and two family practitioners on the panel. Four of the nine panelists were women.

4. **Rating of indications.** The indications and the literature review were then provided to the panelists, who were asked to independently rate each indication for the appropriateness of hysterectomy on a nine-point scale, where 1 = highly inappropriate and 9 = highly appropriate. An indication is "appropriate" if the benefits and positive effects outweigh the risks and negative effects by a sufficient margin that the procedure is worth doing. The ratings took place in two stages: first, independently and alone; second, independently and confidentially after face-to-face discussion.

5. **Analysis of ratings.** The median score of the nine expert ratings is used as the final rating of appropriateness. An indication for hysterectomy is considered *inappropriate* if the median panel rating

is in the 1–3 range, *uncertain* if it is 4–6, and *appropriate* if the median rating is 7–9. An indication is also considered *uncertain* if two or more panelists' ratings are in the 1–3 and two or more panelists' ratings are in the 7–9 range. The final ratings are contained in the companion document, *Hysterectomy: Ratings of Appropriateness* (MR-592/3-AHCPR).

The product of this process is a comprehensive list of indications for hysterectomy that are rated as appropriate, uncertain, or inappropriate. The ratings are detailed, specific, and comprehensive; that is, they attempt to include essentially all clinical situations (other than emergencies and cancer) in which hysterectomy is a treatment option.

Note that the ratings reflect a preponderance of expert opinion, but not necessarily a consensus. A rating of "uncertain" usually meant that the panelists found the evidence to be inadequate to make a definite judgment one way or the other; only occasionally did it reflect disagreement among the panel members.

The appropriateness ratings from the RAND process are difficult to use in clinical practice because of their detail and comprehensiveness. Further, they include every possible indication for hysterectomy as well as consideration of all diagnostic tests and alternative therapies. Accordingly, they have been simplified by grouping similar indications with equivalent ratings and by eliminating redundancy. They were then reviewed and revised by a Clinical Advisory Board consisting of four gynecologist members of the expert panel and a representative from the American College of Obstetricians and Gynecologists.

Use of the Recommendations

Because of the absence of outcome data for most of the indications for hysterectomy, it is not possible to base recommendations for hysterectomy on evidence from the medical literature. Further, the great variation in symptoms, anatomy, and psychosocial factors among women preclude definitive assertions that hysterectomy is or is not indicated in many situations where it might seem to be appropriate. Therefore, the primary purpose of modifying the ratings into recommendations was to identify those potential indications for hysterectomy that were clearly inappropriate except under very unusual circumstances. This represents a subset of the ratings that fell into the inappropriate category (median score of 1–3 without disagreement).

A recommendation of "inappropriate" represents the unanimous agreement of the expert panel that it is wrong to perform hysterectomy in the usual patient with the condition. Individual women may represent exceptions and require different therapy. All other women are considered "possible candidates for hysterectomy."

The category "possible candidate for hysterectomy" is not meant to imply that hysterectomy is indicated in these women, merely that it may be a treatment option. In some cases, hysterectomy may be clearly appropriate, even necessary; in others, seldom appropriate. The full range of expert panel judgments about whether the highly detailed indications were appropriate, uncertain, or inappropriate in the average woman are found in the appropriateness ratings.

The recommendations are presented in two forms for each "chapter" of indications: guiding principles and a graphic algorithm. A chapter consists of all the specific scenarios within an accepted clinical entity, such as endometriosis. For each chapter, the guiding principles appear on the left-hand page and the corresponding algorithm appears on the right-hand page. The terms used in the recommendations are highly specific and were precisely defined by the panel. The definitions are provided with the recommendations for each chapter. The definition for one term used in many of the chapters—endometrial sample—is provided in the box below.

The recommendations are unlike other decision aids or treatment recommendations in that they focus on only one aspect of patient care: the decision to recommend hysterectomy. They are not complete algorithms for diagnosis or treatment, and, therefore, they do not provide specific recommendations for all tests or non-hysterectomy treatments. There are several reasons for this, but the most important is the absence of a clear consensus, even among experts, on the best practice for most of the conditions described here. These recommendations were developed by a group of expert physicians to enumerate the essential evaluative and treatment steps that should be taken before hysterectomy is considered.

The reader should first select the chapter that best describes the clinical condition of the woman. If additional information is needed, refer to the accompanying literature review and ratings documents: *Hysterectomy: A Review of the Literature on Indications, Effectiveness, and Risks* (MR-592/2-AHCPR) and *Hysterectomy: Ratings of Appropriateness* (MR-592/3-AHCPR).

A Cautionary Note

These recommendations represent the group judgment of a panel of experts of the appropriateness of hysterectomy for the *average* woman presenting with the specific set of clinical characteristics embraced in an individual indication. They are not the product of a rigorous risk/benefit analysis because the data for such an analysis do not exist. They cannot, therefore, be followed blindly, nor should they be considered standards of care. Rather, they are recommendations, based on evidence and experience. In individual cases there may be considerations of crucial importance to the decisions not included in the recommendation and that influence a judgment as to appropriateness for a particular woman. This should not occur often; the reason for making the recommendations as comprehensive as possible is to minimize this possibility.

Please note that these recommendations do not address the appropriateness of hysterectomy for emergencies or malignant disease. Also, the expert panel felt that hysterectomy is inappropriate in all instances of benign disease if the woman desires to keep her uterus.

Finally, these recommendations do not take into account individual patient values, such as risk aversion and attitudes toward surgery. Thus, even if hysterectomy is appropriate for average (most) women with a given indication, any individual woman may appropriately opt for non-surgical therapy.

DEFINITION OF ENDOMETRIAL SAMPLE

Endometrial sampling is frequently recommended prior to a decision regarding whether to perform hysterectomy. In women with abnormal uterine bleeding, endometrial sampling is important to identify whether there is a specific condition leading to the bleeding (e.g., endometrial polyp, endometrial hyperplasia, endometrial carcinoma). Several methods are available to obtain endometrial tissue. These include: (1) a blind endometrial biopsy or aspiration curettage; (2) a dilation and curettage; or (3) a hysteroscopy with biopsy. A hysteroscopy with biopsy may provide the most information, inasmuch as there is direct visualization of the endometrium and the biopsy can be directed; however, the expert panel did not recommend it for all women because it is not a technique known to all obstetricians and gynecologists, it is expensive, and it requires more time on the part of both the woman and the physician. Therefore, in these recommendations, any form of endometrial sampling is considered adequate.

Cigna Medical Coverage Policy

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Subject **Hysterectomy**

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Coverage Policy

Cigna covers hysterectomy, with or without salpingo-oophorectomy, as medically necessary for the following indications/conditions:

- uterine leiomyomata (fibroids) when **ALL** of the following medical necessity criteria are met:
  - significant size (i.e., fibroids that have enlarged the uterus to ≥ 12 weeks' gestational size (i.e., at least 14 cm in one dimension as measured by transvaginal ultrasound [US])
  - significant symptoms, as indicated by **ANY ONE** of the following:
    - recurrent profuse bleeding lasting longer than seven days or repetitive periods at less than 21-day intervals, in the absence of other remediable pathology after completion of an appropriate evaluation (e.g., ultrasound, endometrial biopsy, sonohysterogram, hysteroscopy, hysterosalpingogram, or dilation and curettage [D&C])
    - anemia due to chronic uterine bleeding
    - failure of symptoms to respond to uterine artery embolization (UAE), hysteroscopic resection of submucosal fibroid or endometrial ablation
    - chronic lower abdominal or pelvic pain, low back pressure, rectal pressure or bowel dysfunction for which no other cause can be found

- urinary symptoms (e.g., frequent urination) found on evaluation to be due to mass pressure effect and not to intercurrent infection or other etiology

- abnormal (premenopausal) uterine bleeding with **ALL** of the following:

  - bleeding is recurrent (i.e., lasting longer than seven days or repetitive periods at less than 21-day intervals) and unresponsive to medical management, including at least a three- month trial of hormonal manipulation unless contraindicated or not tolerated
  - no evidence of other remediable pathology on diagnostic evaluation of the endometrium completed within the last 24 months by endometrial biopsy or D&C
  - no evidence of other remediable pathology on diagnostic imaging of uterine cavity by US, sonohysterogram, hysteroscopy, hysterosalpingogram
  - alternative therapeutic approaches (e.g., endometrial ablation) have been given careful consideration

- chronic pelvic pain when **ALL** of the following criteria have been met:

  - persistent pain for more than six months that impairs the individual's ability to complete her usual daily activities and is unresponsive to oral contraceptives, analgesics, anti-inflammatory agents, or amenorrheic agents (e.g., gonadotropin-releasing hormone (GnRH) analogs, danazol, Depo-Provera), unless these medications are contraindicated or not tolerated
  - nongynecological sources of pelvic pain (e.g., gastrointestinal, musculoskeletal, psychological, psychosexual and/or urinary) have been excluded
  - no gynecological cause for the pain has been determined after careful evaluation, including a laparoscopic evaluation performed within the past 24 months

- chronic pelvic inflammatory disease that is unresponsive to appropriate medical management

- recurrent, high-grade squamous intraepithelial neoplasia (HGSIL), following failure of conservative surgical therapy (e.g., loop electrosurgical excision procedure [LEEP] or cold knife cone)

- symptomatic pelvic relaxation when **BOTH** of the following are present:

  - second-degree or greater uterine prolapse
  - failure, intolerance, contraindication to, or individual non-acceptance of available nonsurgical options such as the use of a pessary

- when performed in conjunction with laparotomy for adnexal pathology when malignancy is suspected

- cervical, ovarian, fallopian tube, or endometrial cancer

- endometrial hyperplasia with atypia, as demonstrated on endometrial biopsy or D&C, **WITH** failure, contraindication or intolerance (includes individual non-acceptance) of hormonal manipulation

- endometriosis, when **ALL** of the following medical necessity criteria are met:

  - a histological or surgical diagnosis of endometriosis made within the past five years
  - persistent pain for more than six months causing impairment of the individual's ability to participate in her normal daily activities
  - failure, contraindication or intolerance of medical management, including danazol, lupron or other GnRH agonist, oral contraceptives or progestin therapy
  - where applicable, the failure of other appropriate surgical measures to control symptoms

- malignant gestational trophoblastic disease that is unresponsive to conservative medical and/or surgical management

- postpartum hemorrhage that cannot be controlled by conservative therapy (e.g., uterine atony, placenta accreta)

Cigna covers prophylactic hysterectomy as medically necessary for a woman diagnosed with hereditary nonpolyposis colorectal cancer (HNPCC), found to be a carrier of HNPCC–associated mutations, or a member of an HNPCC family as determined by a pattern of occurrence of HNPCC-related cancers.

All individuals undergoing genetic testing for any reason should have both pre- and post-test genetic counseling with a physician or a licensed or certified genetic counselor.

General Background

Hysterectomy, the removal of the uterus, is one of the most commonly performed surgical procedures in the United States. A hysterectomy may be performed with or without an oophorectomy, and is most often done electively for abnormal uterine bleeding or other non-life-threatening indications. For women who require the procedure, the appropriate surgical approach (i.e., abdominal, vaginal, laparoscopic) is determined by anatomical factors, the type of pathology expected, patient preference and physician experience and training (Parker, 2004).

Surgical Techniques
Total Abdominal Hysterectomy (TAH): TAH (with or without salpingo-oophorectomy) is the most commonly performed hysterectomy. Both the uterine fundus and the cervix are removed at the cervico-vaginal junction. The entire uterus, ovaries and fallopian tubes are removed. It may be performed through either a transverse or a vertical abdominal incision, depending on the indications for the procedure and the size of the uterus. This is the procedure of choice for most uterine and ovarian cancers, endometriosis, pelvic pain, large fibroid uteri in which conservation of the cervix is not desired and conditions in which evaluation of the full pelvis and abdomen is required (e.g., pelvic masses or adnexal masses of unknown diagnosis).

Radical Hysterectomy: Radical hysterectomy is a procedure in which the parametrial tissue and the upper vagina are removed in conjunction with the fundus and the cervix. It is primarily indicated in the treatment of early-stage cervical cancer. It carries with it a greater risk for bowel and bladder dysfunction, ureteral injury and subsequent urinary fistula.

Supracervical Hysterectomy: Supracervical hysterectomy can be performed either abdominally or laparoscopically so that conservation of the cervix may be assured. The fundus of the uterus is removed to the level below the uterine vessels, and the cervix is conserved. This procedure is indicated for the patient who desires to keep her cervix for its potential role in sexual function, and who does not have a contraindication (e.g., history of cervical dysplasia, cancer) that would preclude retention of the cervix. It is also indicated for the patient in whom the surgical procedure would be made safer by conservation of the cervix (e.g., obliteration of the cul-de-sac because of advanced endometriosis) and in whom there is no contraindication to its retention. Advantages of this procedure include the greater ease and shorter time required. It is often the preferred surgery for emergency and Cesarean hysterectomies. Retention of the cervix may also result in less vaginal prolapse because of better vaginal support.

The American College of Obstetricians and Gynecologists (ACOG) committee opinion on supracervical hysterectomy states that patients electing this procedure should be carefully screened preoperatively to exclude cervical or uterine neoplasm. These patients should be counseled about the need for long-term follow-up, the possibility of future trachelectomy or removal of the cervical stump, and the lack of data demonstrating clear benefits over total hysterectomy (ACOG, 2007).

Vaginal Hysterectomy: Vaginal hysterectomy is performed entirely through the vagina. The most common indications include uterine prolapse or benign or premalignant conditions (e.g., endometrial hyperplasia or cervical dysplasia) that do not result in unusually large uteri and are not likely to result in significant intra-abdominal adhesions and in which exploration of the upper abdomen is nonessential. Advantages of this procedure are the absence of an abdominal scar, the tendency for a quicker recovery, and a shorter hospital stay. Physical requirements for the procedure include the ability to lie on one's back with legs in stirrups for a

prolonged time, a relatively small and mobile uterus and adequate room in the vagina in which to operate. Thus, for women who have never had children or who are virginal, this option may not be possible. Experienced surgeons can sometimes remove larger uteri with this approach through coring or by removing the uterus in parts.

Laparoscopy-Assisted Vaginal Hysterectomy (LAVH): LAVH combines a vaginal approach with a laparoscopic abdominal approach. This may be appropriate for patients in whom evaluation of the abdomen is indicated (for instance, for grade 1 endometrial cancer), or in whom removal of the ovaries is desired. Although this procedure has the advantages of smaller abdominal scars and shorter hospital stays, it has been shown to have higher rates of complication, and longer operative times than simple abdominal or simple vaginal hysterectomy. Appropriate case selection and high surgical volume are probably the two leading means of ensuring good outcomes. In general, patients should meet the same physical requirements as for simple vaginal hysterectomy, and they should be at low-risk for laparoscopic complication (no history suggestive of the formation of abdominal adhesions, normal weight range and no large pelvic masses). If there is uncertainty about a patient, but upper abdominal access is necessary, laparotomy with abdominal hysterectomy may be the procedure of choice.

According to the ACOG committee opinion on the use of LAVH, prospective randomized trials demonstrate that LAVH is associated with faster recovery, less postoperative pain and similar complication rates when compared to TAH. The position further states that the technique used for hysterectomy should be dictated by the indication for the surgery, patient characteristics, and patient preference. However, most patients requiring hysterectomy should be offered the vaginal approach when technically feasible and medically appropriate (ACOG, 2005).

Total Laparoscopic Hysterectomy (TLH): TLH involves the removal of the entire uterus and cervix through a small abdominal incision under laparoscopic guidance. The indications for TLH include benign gynecological conditions such as fibroids, endometriosis and abnormal uterine bleeding. The procedure may also be performed for malignant indications such as early endometrial cancer (Mettler, et al., 2005). TLH requires a high degree of surgical skill and is done by a limited proportion of gynecologists. In general, it has been reported that minimally invasive procedures take longer to perform; however, estimated blood loss and patient recovery time are typically less.

A number of studies in the literature have compared TLH to various hysterectomy procedures for the treatment of benign and malignant gynecological conditions (Ghezzi, et al., 2005; Garry, et al., 2004; Riberio, et al., 2003), and provided supportive evidence that TLH is technically feasible and can be performed safely in the hands of surgeons who are experienced in operative laparoscopy (Ramirez, et al., 2006; Obermair, et al., 2005; O'Hanlan, et al., 2005; Hoffman, et al., 2005; Seracchioli, et al., 2002).

Guidelines from the National Institute for Clinical Excellence (NICE) state that the current evidence on the safety and efficacy of laparoscopic techniques for hysterectomy appear adequate to support the use of LAVH, TLH, and laparoscopic supracervical hysterectomy. It is further stated that women should be advised of the higher risk of urinary tract injury and bleeding associated with these procedures compared to open surgery (NICE, 2007).

In an update of a Cochrane review, Nieboer et al. (2009) analyzed 34 comparative, parallel-group trials (n=4495) to assess the most beneficial and least harmful surgical approach to hysterectomy for women with benign gynecological conditions. Vaginal hysterectomy was found to have equal or significantly better outcomes on all parameters, including speedier return to normal activities, and fewer febrile episodes or unspecified infections. It was summarized that if vaginal hysterectomy is not possible, laparoscopic hysterectomy may avoid the need for an abdominal procedure. However the length of the surgery increases as the extent of the surgery performed laparoscopically increases (Nieboer, et al. 2009).

Conclusions drawn by ACOG in their committee opinion on the route of hysterectomy for benign disease include the following (No authors listed, 2009):

- Vaginal hysterectomy is the approach of choice whenever feasible, based on its well-documented advantages and lower complication rates.
- The choice of whether to perform prophylactic oophorectomy at the time of hysterectomy is based on the patient's age, risk factors, and informed wishes, but not on the route of hysterectomy.

- Laparoscopic hysterectomy is an alternative to abdominal hysterectomy for those patients in whom a vaginal hysterectomy is not indicated or feasible.

Indications for Hysterectomy

Leiomyoma (Fibroids): The most common indication for hysterectomy remains uterine leiomyoma. Uterine fibroids or leiomyomata are benign tumors of muscle and connective tissue that develop within the wall of the uterus. The size of fibroid tumors varies significantly (e.g., from as small as 1 mm to over 20 cm or eight inches in diameter), and can increase uterine measurements. It is generally accepted that the size of a non-pregnant uterus ranges from 8 cm x 4 cm x 4 cm to 12 cm. A 10-week gestational size uterus measures 12 cm in length, and a 12-week size uterus measures approximately 14 cm or greater in length (Margulies and Miller, 2001). Fibroids can contribute to symptoms related to an enlarging pelvic mass (e.g., urinary frequency or constipation). Although many women do not feel any symptoms with uterine fibroids, they may cause symptoms such as heavy bleeding or painful periods, noncyclic pelvic pain, lower back pain, and pain during sex. A transvaginal or pelvic ultrasound may be performed to confirm the findings of uterine fibroids. In addition, dilatation and curettage or pelvic laparoscopy may be necessary to rule out other potentially malignant conditions.

Abnormal Uterine Bleeding: Abnormal or dysfunctional uterine bleeding (DUB) is another common indication for a hysterectomy. In women of childbearing age, abnormal uterine bleeding includes any change in menstrual period frequency or duration or amount of flow, as well as bleeding between cycles. In postmenopausal women, abnormal uterine bleeding includes vaginal bleeding 12 months or more after the cessation of menses, or unpredictable bleeding in postmenopausal women who have been receiving hormone therapy for 12 months or more. DUB (i.e., anovulatory and ovulatory) is diagnosed by exclusion of these causes.

Medical management of anovulatory DUB may include oral contraceptives and cyclic progestins, as well as a combination of various oral and injectable estrogens and progestins. Surgical management may include hysterectomy or less invasive, uterus-sparing procedures, such as endometrial ablation. A curettage or thorough endometrial aspiration is indicated for women over the age of 35 who have persistent abnormal bleeding or for women with bleeding that is sufficiently severe to produce anemia.

The most difficult management of DUB is treatment of ovulatory women with chronic menorrhagia. For these women, nonsteroidal anti-inflammatory drugs (NSAIDs), progestins, oral contraceptives, danazol, and gonadotropin-releasing hormone (GnRH) analogues are all useful therapeutic modalities. A combination of two or more of these agents is often required to obviate the need for endometrial ablation or hysterectomy.

Pelvic Pain: Chronic pelvic pain (CPP) accounts for approximately 9% of all hysterectomies performed. Dysmenorrhea is perhaps the most common example of recurrent pelvic pain and is defined as a painful cramping sensation in the lower abdomen, often accompanied by other symptoms, such as sweating, tachycardia, headaches, nausea, vomiting, diarrhea, and tremulousness. All these symptoms can occur just before or during the menses. Primary dysmenorrhea begins at or shortly after menarche, and is usually not accompanied by pelvic pathologic conditions. Secondary dysmenorrhea arises later and usually is associated with other pelvic conditions.

In addition, the following may be responsible for recurrent or persistent pelvic pain: incompletely treated pelvic infections, recurrent pelvic infections, endometriosis, and possibly postoperative pelvic adhesions, as well as diseases of the urinary tract and bowel.

According to the American College of Obstetricians and Gynecologists (ACOG), combined oral contraceptives should be considered as a treatment option to decrease pain from primary dysmenorrhea. Gonadotropin-releasing hormone (GnRH) agonists are effective in relieving pelvic pain associated with endometriosis and irritable bowel syndrome, as well as in women with symptoms consistent with endometriosis who do not have endometriosis. Progestins in daily, high doses should be considered as an effective treatment of CPP associated with endometriosis and pelvic congestion syndrome. Nonsteroidal antiinflammatory drugs, including COX-2 inhibitors, should be considered for moderate pain and are particularly effective for dysmenorrhea (ACOG, 2004). Hysterectomy should be reserved for patients who have failed conservative therapy

Some women with CPP also have associated psychosocial problems such as depression, somatization, narcotic dependency, or a history of physical and sexual abuse (Lifford and Barbieri, 2002). Published evidence

suggests a significant association of physical and sexual abuse with various chronic pain disorders. Studies have reported that 40–50% of women with CPP have a history of abuse.

The ACOG guidelines for CPP state that the addition of psychotherapy to medical treatment of CPP should be considered, as the combination appears to improve response over that of medical treatment alone. The guidelines also state that hysterectomy can be considered an effective treatment that results in pain relief for 75–95% of women who have CPP associated with reproductive tract symptoms (ACOG, 2004).

Pelvic Inflammatory Disease (PID): PID refers to an infection of the uterus, fallopian tubes, and other reproductive organs that causes symptoms such as lower abdominal pain. It is a complication of some sexually transmitted diseases (STDs), especially chlamydia and gonorrhea. PID can damage the fallopian tubes and tissues in and near the uterus and ovaries and lead to consequences including infertility, ectopic pregnancy, abscess formation, and chronic pelvic pain. PID is usually treated with antibiotics, but may require surgical intervention for refractory infection or complications such as CPP or scarring (Centers for Disease Control and Prevention [CDC], 2012).

A tubo-ovarian abscess (TOA) is an infection that forms in the fallopian tube and ovary and is one of the more severe complications of PID. TOAs most commonly occur in women of reproductive age and can develop in women who have PID. Clinical presentation of TOA is similar to that of PID with the addition of a pelvic mass often noted on examination or imaging. Treatment of TOAs includes the use of antibiotics and drainage. In patients who fail to respond, laparoscopy or laparotomy is typically performed (Lareau and Beigi, 2008).

Cervical Dysplasia: Dysplasia is a traditional term used to describe varying degrees of cervical intraepithelial neoplasia. The Pap smear has been widely used to screen women for malignant and premalignant cervical dysplasia or disease. Pap smear results may be mild (low-grade), involving approximately one-third of the epithelium (cervical intraepithelial neoplasia [CIN] I); moderate, involving approximately two-thirds of the epithelium (CIN II); or severe (high-grade), involving the full thickness of the epithelium (CIN III). When untreated, high grade cervical dysplasia may progress to cervical cancer over time. Hysterectomy is indicated for high-grade (CIN III) squamous intraepithelial neoplasia (HGSIL), following failure of conservative surgical therapy in conjunction with no desire for childbearing.

Uterine Prolapse (Descensus, Procidentia): Descensus of the uterus and cervix into or through the barrel of the vagina is associated with injury to or relaxation of the pelvic floor muscles. Major symptoms noted by patients with descensus are a feeling of heaviness, fullness or falling out in the perineal area. In cases where the cervix and uterus are low in the vaginal canal, the cervix may be seen protruding from the introitus. A prolapse into the upper barrel of the vagina is first degree, through the vaginal barrel to the region of the introitus is second degree, and out through the introitus is third degree or total.

Medical management of such conditions involves the use of a pessary. Surgical repair for prolapse of the uterus and cervix generally involves a vaginal hysterectomy with anterior and posterior colporrhaphy.

Endometrial Cancer: Adenocarcinoma of the endometrium is mainly a malignancy of postmenopausal women and is increasingly virulent with advancing age. There are no accepted routine screening methods for detecting endometrial cancer in asymptomatic women or in women at increased risk. Even though a routine Pap smear cannot be relied on as a screen for endometrial cancer, this type of malignancy should be suspected in any nonpregnant woman with atypical endometrial cells or in any postmenopausal woman with normal endometrial cells on a Pap smear (Scott, 2003). Abnormal uterine bleeding is the most common initial symptom of endometrial cancer. It is recommended that perimenopausal women with abnormal bleeding undergo an endometrial biopsy.

Endometrial cancer is staged according to the International Federation of Gynecology and Obstetrics (FIGO) staging system. The recommendation is for all medically operable patients with clinical stage I disease, regardless of tumor grade, to undergo an extrafascial TAH and bilateral salpingo-oophorectomy for both staging and therapeutic purposes. A radical hysterectomy may be appropriate in certain circumstances in which the disease is known to involve the cervix or parametrium (Scott, 2003).

Ovarian and Fallopian Tube Cancers: Epithelial ovarian cancer is one of the most common gynecologic malignancies. The most significant risk factor for ovarian cancer is a family history of a first-degree relative

(e.g., mother, daughter, sister) with the disease. Some symptoms that may be suggestive of ovarian cancer include pelvic or abdominal pain, bloating, and urinary urgency or frequency, particularly if these symptoms are new or occur frequently. Ovarian cancer is difficult to diagnose at an earlier, more curable stage because of the location of the ovaries and the biology of most epithelial cancers. Cancer of the Fallopian tube is less common, and is managed with treatments similar to those used for epithelial ovarian cancer. Total hysterectomy and bilateral salpingo-oophorectomy are performed as part of the surgical management of patients with ovarian and fallopian tube cancers (National Comprehensive Cancer Network Guidelines™ [NCCN Guidelines™], 2010).

Endometrial Hyperplasia: Endometrial hyperplasia is generally considered a precursor to endometrial cancer. The condition occurs during periods of long-term unopposed estrogen stimulation, such as anovulation, particularly around the time of menopause. The World Health Organization (WHO) identifies four categories of endometrial hyperplasia according to their premalignant potential: simple, complex, simple with atypia, and complex with atypia.

Mild complex hyperplasia with atypia often responds to progestin therapy and is an option for those women who are interested in preserving the uterus for childbearing. Three months of progestin therapy is the initial recommended therapy (Stenchever, 2001). Since approximately 25–30% of atypical hyperplasia, which is diagnosed via endometrial biopsy, can potentially progress to endometrial cancer, the suggested treatment is hysterectomy when preservation of the uterus is not desired. The more severe the atypia, the less chance it will reverse itself with hormone therapy.

According to the ACOG guidelines for the management of endometrial cancer, atypical endometrial hyperplasia and endometrial cancer should be considered part of a continuum. The diagnosis remains uncertain as long as the uterus is in situ. For women who have completed childbearing, hysterectomy should be recommended for the treatment of atypical endometrial hyperplasia because of the high risk of an underlying cancer. Women who want to maintain fertility may be treated with progestins in an attempt to reverse the lesion (ACOG, 2005).

Endometriosis: Endometriosis is the presence and growth of the glands and stroma of the lining of the uterus in an aberrant or heterotopic location. The classic symptoms of endometriosis are cyclic pelvic pain and infertility. However, approximately one-third of patients with endometriosis are asymptomatic, with the disease being discovered incidentally during an abdominal operation or visualized at laparoscopy for an unrelated problem. Most patients should undergo a diagnostic laparoscopy to establish the nature and extent of endometriosis before therapy. However, if other gynecological conditions, such as chronic pelvic inflammatory disease or neoplasia, have been ruled out, empiric medical therapy for 3–6 months with a GnRH agonist is a reasonable choice.

Surgical treatment is divided into conservative and definitive operations. Conservative surgery involves the resection or destruction of endometrial implants, lysis of adhesions, and attempts to restore normal pelvic anatomy. Definitive surgery involves hysterectomy, which includes the removal of the ovaries, the uterus and all visible ectopic foci of endometriosis.

Adenomyosis: Adenomyosis is caused by the presence of functioning ectopic endometrial tissue in the myometrium. The pathogenesis of adenomyosis remains unclear. Common presenting symptoms include menorrhagia, dysmenorrhea and an enlarged, sometimes tender uterus. Pain may be referred to the back and rectum. The presenting symptoms of adenomyosis overlap with those of other common gynecological disorders such as DUB, uterine leiomyomata and endometriosis. There is also a slightly increased rate of endometrial carcinoma in patients with adenomyosis. There is no proven medical treatment for the condition.

Attempts have been made to establish the diagnosis of adenomyosis preoperatively by transcervical needle biopsy of the myometrium, however the sensitivity of this testing method is reportedly too low to be of practical clinical value. The peer reviewed medical literature suggests that TVU be used as the initial imaging technique in patients suspected of having adenomyosis. Both ultrasound and magnetic resonance imaging (MRI) are useful to assist in differentiating between adenomyosis and uterine myomas in young women desiring future childbearing. Although adenomyosis can be suggested by ultrasound, sonohysterogram and/or hysteroscopy, a definitive diagnosis can usually only be made by histological examination of a hysterectomy specimen. Therefore, hysterectomy is more commonly indicated for the presenting symptoms of adenomyosis such as DUB, uterine leiomyomata and endometriosis.

Gestational Trophoblastic Disease: Gestational trophoblastic disease (GTD) or molar pregnancy comprises a spectrum of diseases characterized by disordered proliferation of chorionic villi. The spectrum of GTD includes:

- Hydatidiform mole (complete or partial)
- Persistent/invasive gestational trophoblastic neoplasia (GTN)
- Choriocarcinoma
- Placental site trophoblastic tumors (PSTT)
- Epithelioid trophoblastic tumor

The last four categories comprise the malignant forms of GTD. Following evacuation of a complete or partial molar pregnancy, the diagnosis of GTN is usually based upon a rising or stable serum level of beta-hCG. In most such cases, the diagnosis is made clinically rather than histologically by examination of tissue. In general, malignant GTD, also called trophoblastic neoplasia, is highly responsive to chemotherapy. For women who desire to retain fertility, more conservative surgical therapy may be considered. Hysterectomy may be considered in the subset of women who have chemotherapy-resistant disease (McGee and Covens, 2012).

Postpartum Hemorrhage: An estimated blood loss of more than 500 milliliters (mL) following a vaginal birth or a loss of more than 1000 mL after cesarean birth has been used for the diagnosis of postpartum hemorrhage. Postpartum hemorrhage is generally classified as primary or secondary, with primary hemorrhage occurring within the first 24 hours of delivery and secondary hemorrhage occurring between 24 hours and 6–12 weeks after giving birth. The management of postpartum hemorrhage may vary, depending on etiology of the bleeding, available treatment options, and the desire for future fertility. Medical treatment options for postpartum hemorrhage in the setting of decreased uterine tone include uterotonics and possibly tamponade of the uterus. Exploratory laparotomy is indicated if uterotonic agents with or without tamponade fail to control bleeding after a vaginal delivery. Surgical management may include uterine curettage, uterine artery ligation, or hysterectomy. Uterine atony and placenta accreta (i.e., the abnormal attachment of the placenta to the inner uterine wall) are the two most common reasons for postpartum hysterectomy (ACOG, 2006).

Hereditary Nonpolyposis Colorectal Cancer (HNPCC): HNPCC is an autosomal dominant condition caused by mutation of one of several DNA mismatch repair (MMR) genes. In addition to colorectal cancer, HNPCC patients and their relatives are at risk of a wide variety of other cancers. The most common is endometrial adenocarcinoma, which affects at least one female member in about 50% of HNPCC pedigrees. Ovarian cancer risk is reported to be 3.5 times higher in HNPCC families than in the general population. There is a lack of controlled studies evaluating the benefit of prophylactic surgery in at-risk HNPCC mutation carriers. However, based upon expert opinion the Cancer Genetics Studies Consortium recommended that prophylactic hysterectomy and bilateral salpingo-oophorectomy be presented as an option for women with HNPCC for prevention of endometrial and ovarian cancer in women known to have HNPCC or to be carriers of HNPCC-associated mutations (Burke, et al., 1997). A systematic review by Lindor et al. (2006) also concluded that given the high risk for endometrial cancer and the moderately increased risk for ovarian cancer in women with HNPCC, prophylactic hysterectomy and oophorectomy is a reasonable option, following a careful discussion of the risks, benefits, and limitations of this procedure (Lindor et al. 2006). For additional information, refer to the Prophylactic Oophorectomy or Salpingo-oophorectomy With or Without Hysterectomy Coverage Policy.

Summary
Hysterectomy is effective in treating a number of gynecological disorders, including symptomatic leiomyoma, abnormal uterine bleeding, endometrial hyperplasia and surgical dysplasia. The procedure may also alleviate symptoms in some women with endometriosis, chronic pelvic pain, pelvic inflammatory disease and pelvic relaxation. Prophylactic hysterectomy with bilateral oophorectomy is recommended for individuals with hereditary nonpolyposis colorectal cancer (HNPCC)-related conditions who have been properly counseled. An appropriate diagnostic evaluation should be performed and alternative treatments considered prior to the recommendation of hysterectomy for any indication.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
58152	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s); with colpo-urethrocystopexy (eg, Marshall-Marchetti-Krantz, Burch)
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
58200	Total abdominal hysterectomy, including partial vaginectomy, with para-aortic and pelvic lymph node sampling, with or without removal of tube(s), with or without removal of ovary(s)
58210	Radical abdominal hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy), with or without removal of tube(s), with or without removal of ovary(s)
58240	Pelvic exenteration for gynecologic malignancy, with total abdominal hysterectomy or cervicectomy, with or without removal of tube(s), with or without removal of ovary(s), with removal of bladder and ureteral transplantations, and/or abdominoperineal resection of rectum and colon and colostomy, or any combination thereof
58260	Vaginal hysterectomy, for uterus 250 grams or less
58262	Vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s), and/or ovary(s)
58263	Vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s), and/or ovary(s), with repair of enterocele
58267	Vaginal hysterectomy, for uterus 250 grams or less; with colpo-urethrocystopexy (Marshall-Marchetti-Krantz type, Pereyra type) with or without endoscopic control
58270	Vaginal hysterectomy, for uterus 250 grams or less; with repair of enterocele
58275	Vaginal hysterectomy, with total or partial vaginectomy
58280	Vaginal hysterectomy, with total or partial vaginectomy; with repair of enterocele
58285	Vaginal hysterectomy, radical (Schauta type operation)
58290	Vaginal hysterectomy, for uterus greater than 250 grams
58291	Vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s)
58292	Vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s), with repair of enterocele
58293	Vaginal hysterectomy, for uterus greater than 250 grams; with colpo-urethrocystopexy (Marshall-Marchetti-Krantz type, Pereyra type) with or without endoscopic control
58294	Vaginal hysterectomy, for uterus greater than 250 grams; with repair of enterocele
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58548	Laparoscopy, surgical, with radical hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy), with removal of tube(s) and ovary(s), if performed
58550	Laparoscopy surgical, with vaginal hysterectomy, for uterus 250 grams or less
58552	Laparoscopy surgical, with vaginal hysterectomy, for uterus 250 grams or less with removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250

	grams
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250g or less
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250g or less; with removal of tube(s) and/or ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250g
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250g; with removal of tube(s) and/or ovary(s)
58951	Resection of ovarian, tubal or primary peritoneal malignancy with bilateral salpingo-oophorectomy and omentectomy; with total abdominal hysterectomy, pelvic and limited para-aortic lymphadenectomy
58953	Bilateral salpingo-oophorectomy with omentectomy, total abdominal hysterectomy and radical dissection for debulking;
58954	Bilateral salpingo-oophorectomy with omentectomy, total abdominal hysterectomy and radical dissection for debulking; with pelvic lymphadenectomy and limited para-aortic lymphadenectomy
58956	Bilateral salpingo-oophorectomy with total omentectomy, total abdominal hysterectomy for malignancy
59525	Subtotal or total hysterectomy after cesarean delivery (List separately in addition to code for primary procedure)

ICD-9-CM Diagnosis Codes	**Description**
154.0	Malignant neoplasm of rectosigmoid junction
179	Malignant neoplasm of uterus, part unspecified
180.0-180.9	Malignant neoplasm of cervix uteri
182.0-182.8	Malignant neoplasm of body of uterus
183.0-183.9	Malignant neoplasm of ovary and other uterine adnexal
184.8	Malignant neoplasm of other specified sites of female genital organs
198.6	Secondary malignant neoplasm of ovary
218.0-218.9	Uterine leiomyoma
219.0-219.9	Other benign neoplasm of uterus
220	Benign neoplasm of ovary
221.0-221.9	Benign neoplasm of other female genital organs
233.1-233.39	Carcinoma in situ of breast and genitourinary system
235.4	Neoplasm of uncertain behavior of retroperitoneum and peritoneum
236.0	Neoplasm of uncertain behavior of uterus
236.1	Neoplasm of uncertain behavior of genitourinary organs, placenta
236.2	Neoplasm of uncertain behavior of ovary
236.3	Neoplasm of uncertain behavior of other and unspecified female genital organ
239.5	Neoplasm of unspecified nature of other genitourinary organs
456.5	Pelvic varices
614.6	Pelvic peritoneal adhesions, female (postoperative) (postinfection)
614.9	Unspecified inflammatory disease of female pelvic organs and tissues
617.0-617.9	Endometriosis
618.00-618.9	Genital prolapse
620.0-620.9	Noninflammatory disorders of ovary, fallopian tube, and broad ligament
621.33	Endometrial hyperplasia with atypia
621.6	Malposition of uterus
622.10	Dysplasia of cervix; unspecified
622.11	Mild dysplasia of cervix
622.12	Moderate dysplasia of cervix
625.0-625.9	Pain and other symptoms associated with female genital organs
626.2	Excessive or frequent menstruation

626.4	Irregular menstrual cycle
626.6	Metrorrhagia
626.8	Other disorder of menstruation and other abnormal bleeding from female genital tract
626.9	Unspecified disorder of menstruation and other abnormal bleeding from female genital tract
627.0	Premenopausal menorrhagia
627.1	Postmenopausal bleeding
627.8	Other specified menopausal and postmenopausal disorder
627.9	Unspecified menopausal and postmenopausal disorder
666.04-666.34	Postpartum hemorrhage
752.32 – 752.39	Other congenital anomaly of uterus
795.00	Abnormal glandular Papanicolaou smear of cervix
795.01	Papanicolaou smear of cervix with atypical squamous cells of undetermined significance (ASC-US)
795.02	Papanicolaou smear of cervix with atypical squamous cells cannot exclude high grade squamous intraepithelial lesion (ASC-H)
795.09	Other abnormal Papanicolaou smear of cervix and cervical HPV

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
Cigna HealthCare	4/15/2008	0128	Hysterectomy
Great-West Healthcare	10/26/2006	05.299.05	Hysterectomy

ICD-10 Urology Guideline Coding Changes

During the ICD-10 Urology review, a new guideline was added to line 228 and 538. HERC staff was directed to find the appropriate ICD-10 codes on line 538 to add to line 228 for the conditions described in the guideline.

> **GUIDELINE NOTE XXX TREATMENT OF BENIGN NEOPLASM OF URINARY ORGANS**
> *Lines 228, 538*
> Treatment of benign urinary system tumors is covered with evidence of bleeding or urinary obstruction. Treatment of 1) oncocytoma which is >5 cm in size or symptomatic and 2) angiomyolipoma (AML) which is >5cm in women of child bearing age or in symptomatic men or women is covered.

Oncocytomas and angiomyolipomas are benign tumors of the kidney (and other organs). The ICD-10 code applicable to both is D30.0.

Recommendations:

1) Add D30.00-D30.02 (Benign neoplasm of kidney) to line 228 CANCER OF KIDNEY AND OTHER URINARY ORGANS
    a. Keep on line 538

2) Remove D30.3, D30.8 and D30.9 from line 228
    a. Added in error, these are benign conditions
    b. Keep on line 538

OR

3) Consider adding entire D30 series (benign neoplasm of urinary organs) to line 228 to reflect coverage of benign tumors with bleeding or urinary obstruction
    a. Keep on line 538

Dermatology ICD-10 follow up issue

Question: What should be the cpt and hcpcs codes placed on the two new dermatology lines based on the Dermatology ICD-10 review?

Question source: ICD-10 Review Dermatology and Plastic Surgery Groups

Issue:
The VBBS/HERC approved the formation of two new lines

1. Line 550 HIDRADENITIS SUPPURATIVA; DISSECTING CELLULITIS OF THE SCALP
2. Line 350 HEMANGIOMAS, COMPLICATED

However, the codes that are supposed to be on these lines have not yet been reviewed in detail by the VBBS.

The hemangiomas are currently located on Line 656 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES so this line was used as a basis of appropriate cpt and hcpcs codes. Similarly, hidradenitis codes were derived from Line 542 DISORDERS OF SWEAT GLANDS.

HERC Staff Recommendations:

1) Rename proposed Line 350 HEMANGIOMAS, COMPLICATED to SUPERFICIAL HEMANGIOMAS, COMPLICATED
   a. Rationale: complicated hemangiomas can happen anywhere (in the lungs, brain) but this line is addressing superficial dermatologic hemangiomas requiring treatment

2) Adopt the following code placement recommendations for the new lines:

A. Line 550 HIDRADENITIS SUPPURATIVA; DISSECTING CELLULITIS OF THE SCALP

ICD-10 Codes	Code description
L73.2	Hidradenitis suppurativa
L66.3	Perifolliculitis capitis abscedens

CPT Codes	Code Description
11450	Excision of skin and subcutaneous tissue for hidradenitis, axillary; with simple or intermediate repair
11451	Excision of skin and subcutaneous tissue for hidradenitis, axillary; with complex repair
11462	Excision of skin and subcutaneous tissue for hidradenitis, inguinal; with simple or intermediate repair
11463	Excision of skin and subcutaneous tissue for hidradenitis, inguinal; with complex repair

Dermatology ICD-10 follow up issue

CPT Codes	Code Description
11470	Excision of skin and subcutaneous tissue for hidradenitis, perianal, perineal, or umbilical; with simple or intermediate repair
11471	Excision of skin and subcutaneous tissue for hidradenitis, perianal, perineal, or umbilical; with complex repair
64650	Chemodenervation of eccrine glands; both axillae
64653	Chemodenervation of eccrine glands; other area(s) (eg, scalp, face, neck), per day
11000	Debridement of extensive eczematous or infected skin; up to 10% of body surface
11001	Debridement of extensive eczematous or infected skin; each additional 10% of the body surface, or part thereof (List separately in addition to code for primary procedure)
11900	Injection, intralesional; up to and including 7 lesions
11901	Injection, intralesional; more than 7 lesions

Also, 98 and 99 cpt codes and hcpcs codes on all surgical lines for office and hospital procedures.

B. Line 350 HEMANGIOMAS, COMPLICATED

ICD-10 Code	Code description
D18.01	Hemangioma of skin and subcutaneous tissue

CPT Code	Code description
11300	Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 0.5 cm or less
11301	Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 0.6 to 1.0 cm
11302	Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 1.1 to 2.0 cm
11303	Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter over 2.0 cm
11305	Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter 0.5 cm or less
11306	Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter 0.6 to 1.0 cm
11307	Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter 1.1 to 2.0 cm
11308	Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter over 2.0 cm
11310	Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.5 cm or less
11311	Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.6 to 1.0 cm
11312	Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 1.1 to 2.0 cm

Dermatology ICD-10 follow up issue

CPT Code	Code description
11313	Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter over 2.0 cm
11400	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 0.5 cm or less
11401	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 0.6 to 1.0 cm
11402	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 1.1 to 2.0 cm
11403	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 2.1 to 3.0 cm
11404	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 3.1 to 4.0 cm
11406	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter over 4.0 cm
11420	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 0.5 cm or less
11421	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 0.6 to 1.0 cm
11422	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 1.1 to 2.0 cm
11423	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 2.1 to 3.0 cm
11424	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 3.1 to 4.0 cm
11426	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter over 4.0 cm
11440	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 0.5 cm or less
11441	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 0.6 to 1.0 cm
11442	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 1.1 to 2.0 cm
11443	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 2.1 to 3.0 cm
11444	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 3.1 to 4.0 cm
11446	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter over 4.0 cm
12031	Repair, intermediate, wounds of scalp, axillae, trunk and/or extremities (excluding hands and feet); 2.5 cm or less
12032	Repair, intermediate, wounds of scalp, axillae, trunk and/or extremities (excluding hands and feet); 2.6 cm to 7.5 cm

Dermatology ICD-10 follow up issue

CPT Code	Code description
13100	Repair, complex, trunk; 1.1 cm to 2.5 cm
13101	Repair, complex, trunk; 2.6 cm to 7.5 cm
13102	Repair, complex, trunk; each additional 5 cm or less (List separately in addition to code for primary procedure)
13120	Repair, complex, scalp, arms, and/or legs; 1.1 cm to 2.5 cm
13121	Repair, complex, scalp, arms, and/or legs; 2.6 cm to 7.5 cm
13122	Repair, complex, scalp, arms, and/or legs; each additional 5 cm or less (List separately in addition to code for primary procedure)
13131	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 1.1 cm to 2.5 cm
13132	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 2.6 cm to 7.5 cm
13133	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; each additional 5 cm or less (List separately in addition to code for primary procedure)
13150	Repair, complex, eyelids, nose, ears and/or lips; 1.0 cm or less
13151	Repair, complex, eyelids, nose, ears and/or lips; 1.1 cm to 2.5 cm
17106	Destruction of cutaneous vascular proliferative lesions (eg, laser technique); less than 10 sq cm
17107	Destruction of cutaneous vascular proliferative lesions (eg, laser technique); 10.0 to 50.0 sq cm
17108	Destruction of cutaneous vascular proliferative lesions (eg, laser technique); over 50.0 sq cm
21011	Excision, tumor, soft tissue of face or scalp, subcutaneous; less than 2 cm
21012	Excision, tumor, soft tissue of face or scalp, subcutaneous; 2 cm or greater
21013	Excision, tumor, soft tissue of face and scalp, subfascial (eg, subgaleal, intramuscular); less than 2 cm
21014	Excision, tumor, soft tissue of face and scalp, subfascial (eg, subgaleal, intramuscular); 2 cm or greater
21552	Excision, tumor, soft tissue of neck or anterior thorax, subcutaneous; 3 cm or greater
21554	Excision, tumor, soft tissue of neck or anterior thorax, subfascial (eg, intramuscular); 5 cm or greater
21931	Excision, tumor, soft tissue of back or flank, subcutaneous; 3 cm or greater
21932	Excision, tumor, soft tissue of back or flank, subfascial (eg, intramuscular); less than 5 cm
21933	Excision, tumor, soft tissue of back or flank, subfascial (eg, intramuscular); 5 cm or greater
22901	Excision, tumor, soft tissue of abdominal wall, subfascial (eg, intramuscular); 5 cm or greater
22902	Excision, tumor, soft tissue of abdominal wall, subcutaneous; less than 3 cm
22903	Excision, tumor, soft tissue of abdominal wall, subcutaneous; 3 cm or greater
23071	Excision, tumor, soft tissue of shoulder area, subcutaneous; 3 cm or greater
23073	Excision, tumor, soft tissue of shoulder area, subfascial (eg, intramuscular); 5 cm or greater
24071	Excision, tumor, soft tissue of upper arm or elbow area, subcutaneous; 3 cm or greater
24073	Excision, tumor, soft tissue of upper arm or elbow area, subfascial (eg, intramuscular); 5

Dermatology ICD-10 follow up issue

CPT Code	Code description
	cm or greater
25071	Excision, tumor, soft tissue of forearm and/or wrist area, subcutaneous; 3 cm or greater
25073	Excision, tumor, soft tissue of forearm and/or wrist area, subfascial (eg, intramuscular); 3 cm or greater
26111	Excision, tumor or vascular malformation, soft tissue of hand or finger, subcutaneous; 1.5 cm or greater
26113	Excision, tumor, soft tissue, or vascular malformation, of hand or finger, subfascial (eg, intramuscular); 1.5 cm or greater
27043	Excision, tumor, soft tissue of pelvis and hip area, subcutaneous; 3 cm or greater
27045	Excision, tumor, soft tissue of pelvis and hip area, subfascial (eg, intramuscular); 5 cm or greater
27337	Excision, tumor, soft tissue of thigh or knee area, subcutaneous; 3 cm or greater
27339	Excision, tumor, soft tissue of thigh or knee area, subfascial (eg, intramuscular); 5 cm or greater
27632	Excision, tumor, soft tissue of leg or ankle area, subcutaneous; 3 cm or greater
27634	Excision, tumor, soft tissue of leg or ankle area, subfascial (eg, intramuscular); 5 cm or greater
28039	Excision, tumor, soft tissue of foot or toe, subcutaneous; 1.5 cm or greater
28041	Excision, tumor, soft tissue of foot or toe, subfascial (eg, intramuscular); 1.5 cm or greater
40500	Vermilionectomy (lip shave), with mucosal advancement
40510	Excision of lip; transverse wedge excision with primary closure
40520	Excision of lip; V-excision with primary direct linear closure
40525	Excision of lip; full thickness, reconstruction with local flap (eg, Estlander or fan)
40527	Excision of lip; full thickness, reconstruction with cross lip flap (Abbe-Estlander)
40530	Resection of lip, more than one-fourth, without reconstruction
40810	Excision of lesion of mucosa and submucosa, vestibule of mouth; without repair
40812	Excision of lesion of mucosa and submucosa, vestibule of mouth; with simple repair
40814	Excision of lesion of mucosa and submucosa, vestibule of mouth; with complex repair
40816	Excision of lesion of mucosa and submucosa, vestibule of mouth; complex, with excision of underlying muscle
40820	Destruction of lesion or scar of vestibule of mouth by physical methods (eg, laser, thermal, cryo, chemical)
41116	Excision, lesion of floor of mouth
41826	Excision of lesion or tumor (except listed above), dentoalveolar structures; with simple repair
42104	Excision, lesion of palate, uvula; without closure
42106	Excision, lesion of palate, uvula; with simple primary closure
42107	Excision, lesion of palate, uvula; with local flap closure
42160	Destruction of lesion, palate or uvula (thermal, cryo or chemical)
42808	Excision or destruction of lesion of pharynx, any method
69145	Excision soft tissue lesion, external auditory canal

Also the 98 and 99 cpt office, telephonic, and hospital and hcpcs consultation codes (included on all surgical lines)

Section 7

Coverage Guidance Review

CG – Management of Chronic Otitis Media with Effusion in Children

Question: How should the HERC approved Coverage Guidance – Management of chronic otitis media with effusion in children—be incorporated into the Prioritized List?

Question source: Health Evidence Review Commission

Issue: HERC approved the Coverage Guidance: Management of chronic otitis media with effusion in children in October, 2012. This coverage guidance needs to be evaluated for application within the Prioritized List. There were some concerns with operationalizing the guideline note language, Staff has worked with DMAP to identify appropriate language.

From the January 10, 2013 VBBS meeting

> **Discussion:** Livingston introduced a summary of changes recommended to bring the Prioritized List into agreement with the HERC Coverage Guidance on management of chronic otitis media in children. There was discussion about when the co-morbidity rule should be applied for ear tubes. The group consensus was that the mentioned high risk groups (children with Down's syndrome, craniofacial anomalies, or cleft palate or children with documented speech and language delay with hearing loss and chronic otitis media) should have tubes covered. There was discussion about putting ear tube procedure codes on lines to pair with these diagnoses, but it was noted that providers would not pair the high risk condition, but rather chronic otitis media in these cases. The decision was that these high risk groups should have coverage explicitly called out in the guideline rather than using the co-morbidity rule. Various wording options were debated.
>
> **Actions:**
>
> 1) HERC staff to work with Drs. Kirk and Shaffer to refine guideline wording and bring back to a future meeting as a straightforward issue.

CG – Management of Chronic Otitis Media with Effusion in Children

HERC Coverage Guidance

Antibiotic and other medication therapy (including antihistamines, decongestants, and nasal steroids) should not be covered for children with children with otitis media with effusion (OME) (without another appropriate diagnosis).

There should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented persistent hearing loss is greater than or equal to 25dB in the better hearing ear, referral for tympanstomy surgery may be covered, given short, but not long-term, improvement in hearing.

Formal audiometry should be covered for children with chronic OME present for 3 months or longer. Children with language delay, learning problems, or significant hearing loss should have hearing testing covered initially upon diagnosis. Children with chronic OME who are not at risk for language or developmental delay should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

Adenoidectomy should not be covered at the time of the first pressure equalization tube insertion.

Patients with craniofacial anomalies, Down's syndrome, cleft palate, and patients with speech and language delay along with hearing loss should have coverage based on an individualized treatment plan.

Current Prioritized List status:

Line:	**383**
Condition:	HEARING LOSS - AGE 5 OR UNDER (See Guideline Notes 64,65,76)
Treatment:	MEDICAL THERAPY INCLUDING HEARING AIDS
ICD-9:	388.00,388.02-388.2,388.40-388.5,388.8,389.00-389.9,V53.2
CPT:	69424,69433,69714,69715,92590-92595,92597,98966-98969,99051,99060,99070,99078,99201-99360,99366, 99374,99375,99379-99412,99429-99444,99468-99480,99605-99607
HCPCS:	G0396,G0397,G0406-G0408,G0425-G0427,S0270-S0274

Line:	**502**
Condition:	CHRONIC OTITIS MEDIA (See Guideline Notes 51,64,65,76)
Treatment:	PE TUBES/ADENOIDECTOMY/TYMPANOPLASTY, MEDICAL THERAPY
ICD-9:	380.50-380.53,381.10-381.89,382.1-382.3,382.9,383.1,383.20-383.31,383.9,384.20-384.9
CPT:	42830-42836,69210-69222,69310,69400-69511,69601-69650,69700,69801,69905,69910,69979,92562-92565, 92571-92577,92590,92591,98966-98969,99051,99060,99070,99078,99201-99360,99366,99374,99375,99379-99412,99429-99444,99468-99480,99605-99607
HCPCS:	G0396,G0397,G0406-G0408,G0425-G0427,S0270-S0274

Chronic otitis media is included on line 502. Currently, guideline note 51 applies to Line 502 only. The tympanostomy codes are scheduled to be removed from Line 383.

GUIDELINE NOTE 51, CHRONIC OTITIS MEDIA WITH EFFUSION

CG – Management of Chronic Otitis Media with Effusion in Children

Line 502

Antibiotic and other medication therapy are not indicated for children with chronic otitis media with effusion (OME). Children with chronic OME present for 3 months or longer or with language delay, learning problems, or significant hearing loss at any time should have hearing testing. Children with chronic OME who are not at risk should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

For the child who has had chronic OME and who has a hearing deficiency in the better-hearing ear of 25 dB or greater, myringotomy with tube insertion recommended after a total of 4 to 6 months of effusion with a documented hearing deficit.

Adenoidectomy is an appropriate surgical treatment for chronic OME in children over 3 years with their second set of tubes. First time tubes are not an indication for an adenoidectomy.

CPT codes

<table>
<tr><th>Code</th><th>Description</th><th>Line Placement</th></tr>
<tr><td>69424</td><td>Ventilating tube removal requiring general anesthesia</td><td><table><tr><th>Line</th><th>Condition</th></tr><tr><td>178</td><td>ACUTE MASTOIDITIS</td></tr><tr><td>308</td><td>COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT</td></tr><tr><td>325</td><td>CLEFT PALATE AND/OR CLEFT LIP</td></tr><tr><td>405</td><td>CHOLESTEATOMA; INFECTIONS OF THE PINNA</td></tr><tr><td>418</td><td>ACUTE OTITIS MEDIA</td></tr><tr><td>502</td><td>CHRONIC OTITIS MEDIA</td></tr></table></td></tr>
<tr><td>69433</td><td>Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia</td><td><table><tr><th>Line</th><th>Condition</th></tr><tr><td>178</td><td>ACUTE MASTOIDITIS</td></tr><tr><td>325</td><td>CLEFT PALATE AND/OR CLEFT LIP</td></tr><tr><td>405</td><td>CHOLESTEATOMA; INFECTIONS OF THE PINNA</td></tr><tr><td>418</td><td>ACUTE OTITIS MEDIA</td></tr><tr><td>502</td><td>CHRONIC OTITIS MEDIA</td></tr></table></td></tr>
<tr><td>69436</td><td>Tympanostomy (requiring insertion of ventilating tube), general anesthesia</td><td>Same as 69433</td></tr>
</table>

CG – Management of Chronic Otitis Media with Effusion in Children

HERC Staff Recommendations:

1. Make the following changes to Guideline Note 51

GUIDELINE NOTE 51, CHRONIC OTITIS MEDIA WITH EFFUSION

Line 383, 502

Antibiotic and other medication therapy (including antihistamines, decongestants, and nasal steroids) are not indicated for children with chronic otitis media with effusion (OME) (without another appropriate diagnosis).

There should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented hearing loss is greater than or equal to 25dB in the better hearing ear, tympanostomy surgery may be indicated, given short- but not long- term improvement in hearing. Formal audiometry is indicated for c~~C~~hildren with chronic OME present for 3 months or longer. ~~or~~ Children with language delay, learning problems, or significant hearing loss ~~at any time~~ should have hearing testing upon diagnosis. Children with chronic OME who are not at risk for language delay (such as those with hearing loss <25dB in the better hearing ear) or developmental delay (should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

Adenoidectomy is not indicated at the time of first pressure equalization tube insertion. It may be indicated in ~~is an appropriate surgical treatment for chronic OME~~ in children over 3 years ~~with~~ who are having their second set of tubes.

Patients with craniofacial anomalies, Down's syndrome, and cleft palate, or documented speech and language delay along with hearing loss and chronic otitis media with effusion are intended to be included on Line 383. Otherwise hearing loss associated with chronic otitis media with effusion is included on Line 502.

2. Add back tympanostomy codes (69424, 69433, 69436) to *Line 383 Hearing Loss – Age 5 or Under*
3. Do not add tympanstomy codes to cleft palate line 325 (or other specified conditions)

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: MANAGEMENT OF CHRONIC OTITIS MEDIA WITH EFFUSION IN CHILDREN

DATE: 10/11/2012

HERC COVERAGE GUIDANCE

Antibiotic and other medication therapy (including antihistamines, decongestants, and nasal steroids) should not be covered for children with children with otitis media with effusion (OME) (without another appropriate diagnosis).

There should be a 3 to 6 month watchful waiting period after diagnosis of otitis media with effusion, and if documented persistent hearing loss is greater than or equal to 25dB in the better hearing ear, referral for tympanstomy surgery may be covered, given short, but not long-term, improvement in hearing.

Formal audiometry should be covered for children with chronic OME present for 3 months or longer. Children with language delay, learning problems, or significant hearing loss should have hearing testing covered initially upon diagnosis. Children with chronic OME who are not at risk for language or developmental delay should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

Adenoidectomy should not be covered at the time of the first pressure equalization tube insertion.

Patients with craniofacial anomalies, Down's syndrome, cleft palate, and patients with speech and language delay along with hearing loss should have coverage based on an individualized treatment plan.

Note: Coverage guidance for recurrent acute otitis media is addressed in a separate document.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCES

Effros, R., & Little, A. (2010). *Pressure equalization tubes in children.* (Produced for the Medicaid Evidence-based Decision Project). Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

Key Sources Cited in MED Report:

American Academy of Family Physicians, American Academy of Otolaryngology – Head and Neck Surgery, & American Academy of Pediatrics (AAFP/AAOHNS/AAP) Subcommittee on Otitis Media with Effusion. (2004). Clinical Practice Guideline: Otitis Media with Effusion. *Pediatrics, 113*(5), 1412-1429.

Griffin, G., Flynn, C.A., Bailey, R.E., & Schultz, J.K. (2006). Antihistamines and/or decongestants for otitis media with effusion (OME) in children. *Cochrane Database of Systematic Reviews*, *4*(CD003423), 1-44.

Kay, D.J., Nelson, M., & Rosenfeld, R.M. (2001). Meta-analysis of tympanostomy tube sequelae. *Otolaryngology-Head and Neck Surgery*, *124*, 374-380.

Leach, A.J., & Morris, P.S. (2006). Antibiotics for the prevention of acute and chronic suppurative otitis media in children. *Cochrane Database of Systematic Reviews*, *4*(CD004401), 1-70.

Lous, J., Burton, M.J., Felding, J., Ovesen, T., Rovers, M., & Williamson, I. (2005). Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. *Cochrane Database of Systematic Reviews*, *1* (CD001801), 1-58.

Mandel, E.M., & Casselbrant, M.L. (2006). Recent developments in the treatment of otitis media with effusion. *Drug, 66*(12), 1545-1576.

McDonald, S., Langton Hewer, C.D., & Nunez, D.A. (2008). Grommets (ventilation tubes) for recurrent acute otitis media in children. *Cochrane Database of Systematic Reviews*, *4*(CD 004741), 1-14.

National Collaborating Centre for Women's and Children's Health. (2008). Surgical management of otitis media with effusion in children. London: National Institute for Health and Clinical Excellence (NICE). Retrieved July 6, 2012, from www.nice.org.uk/nicemedia/pdf/CG60NICEguideline.pdf

Perera, R., Haynes, J., Glasziou, P.P., & Heneghan, C.J. (2006). Autoinflation for hearing loss associated with otitis media with effusion. *Cochrane Database of Systematic Reviews, 4*(CD006285), 1-28.

Rovers, M.M., Black, N., Browning, G.G., Maw, R., Zielhuis, G.A., & Haggard, M.P. (2005). Grommets in otitis media with effusion: an individual patient data meta-analysis. *Archives of Diseases of Childhood*, *90*(5), 480-485.

Simpson, S.A., Thomas, C.L., van der Linden, M., MacMillan, H., van der Wouden, J.C., & Butler, C.C. (2007). Identification of children in the first four years of life for early treatment for otitis media with effusion. *Cochrane Database of Systemic Reviews*, *1*(CD004163), 1-24.

Thomas, C.L., Simson, S., Butler, C., & van der Voort, J. (2006). Oral or topical nasal steroids for hearling loss associated with otitis media with effusion in children. *Cochrane Database of Systemic Reviews*, *3*(CD001935), 1-26.

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Otitis media is one of the most frequent infections in children and is a leading cause of both visits to the physician and use of antibiotics in this population. The direct costs of otitis media are estimated at $3 to 5 billion per year in the US. Recurrent infections or chronic fluid in the middle ear can cause hearing deficits, and there is concern that in a rapidly developing child, this could lead to language and other developmental problems.

Pressure equalization (PE) tubes are small plastic or metal tubes that are surgically inserted into the tympanic membrane to allow for drainage of the fluid from the middle ear with the goal of improved hearing. The hope is that if hearing is improved, then language and other developments can be optimized. One of the challenges of determining which children require PE tube placement is that not all middle ear disease is associated with hearing loss, and even the presence of a mild to moderate hearing loss from a middle ear effusion does not necessarily translate into later speech or language delays in children. Further, the high rates of spontaneous resolution of both acute otitis media and middle ear effusions, and the fact that most PE tubes only remain in the ear drum for 6-12 months, may lessen the potential benefit of PE tube insertion.

Evidence Review

There is evidence that PE tubes decrease the duration of otitis media with effusion (OME) over the first year. In addition, PE tubes provide short-term (three to six month)

improvements in hearing, but this advantage dissipates by 12 months. Overall, there do not seem to be consistent benefits in language and development as a result of PE tube placement for OME. The most common complication of PE tubes appears to be otorrhea, which can result in increased use of oral or topical antibiotics. Tympanosclerosis and retraction pockets of the tympanic membrane are also complications of PE tubes, but their clinical significance remains uncertain. Limited evidence suggests that children with PE tubes sustain higher costs in follow-up, in addition to the costs of the procedure itself, without consistent, measurable benefits in language and development.

There are no clear risk factors that identify children who should have PE tubes placed. Some evidence suggests that children with poor baseline hearing (i.e., >25 dB) and those in daycare obtain more of a hearing benefit from PE tubes. In addition, there is limited evidence that children with baseline language or other developmental delays and hearing loss may benefit from earlier PE tube placement.

Overall, the literature suggests that watchful waiting for at least three months is an appropriate initial step in the management of OME. The literature is less clear on management following this initial three months, with some evidence suggesting that even waiting as long as six months may not have deleterious effects on language and development in many children. In terms of other treatment options, there is no evidence that antihistamines, decongestants or nasal steroids are effective treatments for OME.

Adenoidectomy may improve middle ear effusions at six months but does not lead to significant improvements in hearing or in recurrent acute otitis media. Autoinflation may have some benefits in terms of resolution of effusion but may be difficult to use in young patients who might not be cooperative with the treatment. Oral steroids show short-term benefits for OME but fail to sustain these improvements over the longer term. Oral antibiotics may also improve OME in the short term, but the low quality of the evidence does not allow for definitive conclusions. Prophylactic antibiotics are also modestly effective at decreasing the number of episodes of acute otitis media in children with recurrent disease. There is concern for the development of antibiotic resistance with their chronic use, and despite the modest benefits, their use for recurrent acute otitis media and OME has declined.

Guidelines

Two guidelines that address the surgical management of OME (a joint guideline produced by the American Academy of Family Physicians, American Academy of Otolaryngology – Head and Neck Surgery, and American Academy of Pediatrics [AAFP/AAOHNS/AAP]; a National Institute for Health and Clinical Excellence [NICE] guideline produced by the National Collaborating Centre for Women’s and Children’s

Health) provide similar but slightly different recommendations regarding the management of children with OME. Both recommend monitoring children for the first three months of middle ear effusion and evaluating the child's hearing if the effusion remains at three months. However, NICE recommends hearing testing both at the time of initial diagnosis, and after three months, while the AAFP/ AAOHNS/AAP guideline recommends hearing testing only after OME has been present for three months, unless there is language delay, learning problems or hearing loss is suspected. In addition, language testing is recommended for any child with a documented hearing loss by the AAFP/ AAOHNS/AAP guideline, but not mentioned by the NICE guideline. In addressing this, the text of the evidence review states the following: "A proportion of children referred with suspected OME will also have underlying sensorineural or permanent conductive hearing loss. The GDG [Guideline Development Group] wished to emphasize the need to identify any such component."

Regarding surgical management, the NICE guideline suggests that any child with persistent OME at three months who has a hearing threshold worse than 25 dB should be referred for PE tubes, and if tubes are contraindicated or not desired, then the child should be offered hearing aids and other educational/behavioral interventions. They note that surgical intervention for some children at hearing loss less than 25 to 30 dB may be considered if hearing loss would be expected to significantly impact behavior or development. They specifically identify children with Down syndrome and cleft palate as needing comprehensive specialty care and hearing evaluation, but do not make specific recommendations regarding the timing or use of PE tubes. With regard to the hearing loss level, the text of the evidence review states the following: "Persistent and/or fluctuating OME, resulting in a hearing loss of 25–30 dBHL or greater may have adverse effects on a child's speech and language development, behaviour, emotional development and school progress. *This 25–30 dBHL value is of necessity somewhat notional.* (italics added) Hearing levels fluctuate with time and would not predict the impact precisely even if the hearing history over time were known, because of differing susceptibilities."

In contrast, the AAFP/ AAOHNS/AAP guideline recommends a risk-based approach, in which children at risk for or with language or other developmental delay should be referred more promptly for PE tubes. In children at low risk for delays, the guidelines recommend watchful waiting and monitoring every three to six months until the effusion disappears and referral if significant hearing loss develops or if language or other developmental delays appear. They divide hearing loss into three classes with different actions recommended for each level:

Hearing Level	Recommended Action
≥ 40 dB (moderate hearing loss)	Comprehensive audiologic exam and if hearing loss persists at this level, surgery recommended.
21-39 dB (mild hearing loss)	Comprehensive audiologic exam. Individualize based on effusion duration, severity of hearing loss, parent/caregiver preference: can include optimizing listening and learning environment. Repeat hearing testing in 3-6 months if otitis media with effusion persists and tympanostomy tubes have not been placed.
≤ 20 dB (normal hearing)	Repeat hearing test in 3-6 months if otitis media with effusion persists.

The guideline states this recommendation is based on RCTs and observational studies, with a preponderance of benefit over harm. However, specific citations are not provided that pertain directly to the hearing levels noted above. The text of the guideline does provide citations for the following:

"Asymptomatic OME usually resolves spontaneously, but resolution rates decrease the longer the effusion has been present and relapse is common. Risk factors that make spontaneous resolution less likely include:

- Onset of OME in the summer or fall season,
- Hearing loss more than 30-dB HL in the better hearing ear,
- History of prior tympanostomy tubes, and
- Not having had an adenoidectomy."

Overall Summary

Pressure equalization tubes likely decrease the duration of middle ear effusion over the first year. They also provide short-term improvement in hearing that dissipates by 12 months, resulting in no long-term benefits in language and development as a result of PE tube placement for OME. There are no clear risk factors that identify children who should have PE tubes placed. Some evidence suggests that children with poor baseline hearing (i.e., >25 dB) obtain more of a hearing benefit from PE tubes. Watchful waiting for at least three months and possibly up to six is an appropriate initial step in the management of OME. There is no evidence that antihistamines, decongestants or nasal steroids are effective treatments for OME. Adenoidectomy may improve middle ear effusions at six months but does not lead to significant improvements in hearing or in recurrent acute otitis media. Autoinflation may have some benefits in terms of resolution of effusion, while oral steroids and antibiotics show short-term benefit for OME, but longer term improvement is either not sustained or is uncertain. Prophylactic antibiotics

modestly decrease the number of episodes of acute otitis media in children with recurrent disease.

PROCEDURE

Placement of pressure equalization tubes
Pharmacotherapy
Autoinsufflation

DIAGNOSES

Acute otitis media
Chronic otitis media with effusion

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
381.1	Chronic serous otitis media
381.10	… simple or unspecified
381.19	Other chronic serous otitis media
381.2	Chronic mucoid otitis media
381.20	… simple or unspecified
381.29	Other chronic mucoid otitis media
381.3	Other and unspecified chronic nonsuppurative otitis media
381.4	Nonsuppurative otitis media, not specified as acute or chronic
382.1	Chronic tubotympanic suppurative otitis media
382.2	Chronic atticoantral suppurative otitis media
382.3	Unspecified chronic suppurative otitis media
382.4	Unspecified suppurative otitis media
382.9	Unspecified otitis media
315.34	Speech and language developmental delay due to hearing loss
389.00	Conductive hearing loss unspecified
389.03	Conductive hearing loss middle ear
389.05	Conductive hearing loss unilateral
389.06	Conductive hearing loss bilateral
389.08	Conductive hearing loss of combined types
389.2	Mixed conductive and sensorineural hearing loss
389.20	Mixed hearing loss, unspecified
389.21	Mixed hearing loss, unilateral
389.22	Mixed hearing loss, bilateral
389.9	Unspecified hearing loss
ICD-9 Volume 3 (Procedure Codes)	
None	
CPT Codes	
42820	Tonsillectomy and adenoidectomy; younger than age 12

CODES	DESCRIPTION
42821	Tonsillectomy and adenoidectomy; age 12 and over
42830	Adenoidectomy, primary; younger than age 12
42831	Adenoidectomy, primary; age 12 and over
42835	Adenoidectomy, secondary; younger than age 12
42836	Adenoidectomy, secondary; age 12 and over
69433	Tympanostomy (requiring insertion of ventilating tube, local or topical anesthesia)
69436	Tympanostomy (requiring insertion of ventilating tube, general anesthesia)
69424	Ventilating tube removal requiring general anesthesia
HCPCS Codes	
None	

Note: Inclusion on this list does not guarantee coverage

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

CG - Management of Recurrent Acute Otitis Media in Children

Question: How should the Coverage Guidance - *MANAGEMENT OF RECURRENT ACUTE OTITIS MEDIA IN CHILDREN* be applied to the Prioritized List?

Question source: Evidence-based Guideline Subcommittee

Current Prioritized List Status:

Line 418 ACUTE OTITIS MEDIA

Line:	**418**
Condition:	ACUTE OTITIS MEDIA (See Guideline Notes 29,64,65,76)
Treatment:	MEDICAL AND SURGICAL TREATMENT
ICD-9:	381.00-381.06,381.51,381.81-381.9,382.00-382.02,382.4-382.9,384.00-384.09,993.0
CPT:	69210,69420-69436,98966-98969,99051,99060,99070,99078,99201-99360,99366,99374,99375,99379-99412, 99429-99444,99468-99480,99605-99607
HCPCS:	G0396,G0397,G0406-G0408,G0425-G0427,S0270-S0274

GUIDELINE NOTE 29, TYMPANOSTOMY TUBES IN ACUTE OTITIS MEDIA
Line 418
Tympanostomy tubes (69436) are only included on this line as treatment for 1) recurrent acute otitis media (three or more episodes in six months or four or more episodes in one year) that fail appropriate medical management, 2) for patients who fail medical treatment secondary to multiple drug allergies or who fail two or more consecutive courses of antibiotics, or 3) complicating conditions (immunocompromised host, meningitis by lumbar puncture, acute mastoiditis, sigmoid sinus/jugular vein thrombosis by CT/MRI/MRA, cranial nerve paralysis, sudden onset dizziness/vertigo, need for middle ear culture, labyrinthitis, or brain abscess). Patients with craniofacial anomalies, Down's syndrome, cleft palate, and patients with speech and language delay may be considered for tympanostomy with their first episode of acute otitis media.

Adenoidectomy codes do not currently pair on Line 418.

Line 502
Condition: CHRONIC OTITIS MEDIA
Treatment: PE TUBES/ADENOIDECTOMY/TYMPANOPLASTY, MEDICAL THERAPY

Code	Code Description
380.50	Acquired stenosis of external ear canal, unspecified as to cause
380.51	Acquired stenosis of external ear canal secondary to trauma
380.52	Acquired stenosis of external ear canal secondary to surgery
380.53	Acquired stenosis of external ear canal secondary to inflammation
381.10	Chronic serous otitis media, simple or unspecified
381.19	Other chronic serous otitis media
381.20	Chronic mucoid otitis media, simple or unspecified
381.29	Other chronic mucoid otitis media
381.3	Other and unspecified chronic nonsuppurative otitis media
381.4	Nonsuppurative otitis media, not specified as acute or chronic

Code	Code Description
381.50	Eustachian salpingitis, unspecified
381.51	Acute Eustachian salpingitis
381.52	Chronic Eustachian salpingitis
381.60	Obstruction of Eustachian tube, unspecified
381.61	Osseous obstruction of Eustachian tube
381.62	Intrinsic cartilagenous obstruction of Eustachian tube
381.63	Extrinsic cartilagenous obstruction of Eustachian tube
381.7	Patulous Eustachian tube
381.81	Dysfunction of Eustachian tube
381.89	Other disorders of Eustachian tube
382.1	Chronic tubotympanic suppurative otitis media
382.2	Chronic atticoantral suppurative otitis media
382.3	Unspecified chronic suppurative otitis media
382.9	Unspecified otitis media
383.1	Chronic mastoiditis
383.20	Petrositis, unspecified
383.21	Acute petrositis
383.22	Chronic petrositis
383.30	Postmastoidectomy complication, unspecified
383.31	Mucosal cyst of postmastoidectomy cavity
383.9	Unspecified mastoiditis
384.20	Perforation of tympanic membrane, unspecified
384.21	Central perforation of tympanic membrane
384.22	Attic perforation of tympanic membrane
384.23	Other marginal perforation of tympanic membrane
384.24	Multiple perforations of tympanic membrane
384.25	Total perforation of tympanic membrane
384.81	Atrophic flaccid tympanic membrane
384.82	Atrophic nonflaccid tympanic membrane
384.9	Unspecified disorder of tympanic membrane

Coverage Guidance box:

Prophylactic antibiotics should be covered for recurrent acute otitis media.*

Tympanostomy tubes may be covered for acute otitis media only for recurrent acute otitis media.

Adenoidectomy or adenotonsillectomy should not be covered for the treatment of recurrent acute otitis media.

CG - Management of Recurrent Acute Otitis Media in Children

**Recurrent acute otitis media is defined here as three or more episodes in six months or four or more episodes in one year.*

Note: Coverage guidance for chronic otitis media with effusion is addressed in a separate document.

OHP Managed Care Medical director input

One of the challenges with the current language is that for those groups listed with specific comorbid conditions (e.g. speech delay and craniofacial anomalies) it allows for them to have tympanostomy tubes with a single episode of AOM. However, by the time the referral is made and claim is sent, the AOM has usually resolved. Therefore the language becomes challenging to interpret.

The concurrent wording for the chronic otitis media guideline being reviewed at this meeting is as follows:

> Patients with craniofacial anomalies, Down's syndrome, and cleft palate, or documented speech and language delay along with hearing loss and chronic otitis media with effusion are intended to be included on Line 383. Otherwise hearing loss associated with chronic otitis media with effusion is included on Line 502.

HERC Staff Assessment

The current Prioritized List is fairly consistent with the approved coverage guidance, however, has additional language about those failing medical treatment with multiple drug allergies or those with complicating conditions. The Coverage Guidance is silent on these groups. Additionally, the List currently language has some implementation concerns given that a single episode of AOM in the past is sufficient to justify tympanostomy tubes in certain populations.

Recommendations:

OPTION 1:

1) Make no change to the Prioritized List

OPTION 2:

GUIDELINE NOTE 29, TYMPANOSTOMY TUBES IN ACUTE OTITIS MEDIA
Line 418
Tympanostomy tubes (69436) are only included on this line as treatment for 1) recurrent acute otitis media (three or more episodes in six months or four or more episodes in one year) that fail appropriate medical management, 2) for patients who fail medical treatment secondary to multiple drug allergies or who fail two or more consecutive courses of antibiotics, or 3) complicating conditions (immunocompromised host, meningitis by lumbar puncture, acute mastoiditis, sigmoid sinus/jugular vein thrombosis by CT/MRI/MRA, cranial nerve paralysis, sudden onset dizziness/vertigo, need for middle ear culture, labyrinthitis, or brain abscess). Patients with craniofacial anomalies, Down's syndrome, cleft palate, and patients with speech and language delay may be considered for tympanostomy if unresponsive to appropriate medical treatment or having recurring infections (without needing to meet the strict "recurrent" definition above). ~~with their first episode of acute otitis media.~~

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: MANAGEMENT OF RECURRENT ACUTE OTITIS MEDIA IN CHILDREN

DRAFT FOR VBBS 3/14/13

HERC COVERAGE GUIDANCE

Prophylactic antibiotics should be covered for recurrent acute otitis media.*

Tympanostomy tubes may be covered for acute otitis media only for recurrent acute otitis media.

Adenoidectomy or adenotonsillectomy should not be covered for the treatment of recurrent acute otitis media.

**Recurrent acute otitis media is defined here as three or more episodes in six months or four or more episodes in one year.*

Note: Coverage guidance for chronic otitis media with effusion is addressed in a separate document.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCES

Leach, A.J., & Morris, P.S. (2006). Antibiotics for the prevention of acute and chronic suppurative otitis media in children. *Cochrane Database of Systematic Reviews*, *4*(CD004401), 1-70. [Assessed as up-to-date: 5 AUG 2010]. Retrieved September 27, 2012, from http://summaries.cochrane.org/CD004401/antibiotics-to-prevent-acute-ear-infections-in-children

McDonald, S., Langton Hewer, C.D., & Nunez, D.A. (2008). Grommets (ventilation tubes) for recurrent acute otitis media in children. *Cochrane Database of Systematic Reviews*, *4*(CD 004741), 1-14. [Assessed as up-to-date: 10 JAN 2011]. Retrieved September 27, 2012, from http://summaries.cochrane.org/CD004741/grommets-ventilation-tubes-for-recurrent-acute-otitis-media-in-children

Shekelle PG, Takata G, Newberry SJ, Coker T, Limbos M, Chan LS, et al. (2010). *Management of Acute Otitis Media: Update.* Evidence Report/Technology Assessment No. 198. (Prepared by the RAND Evidence-Based Practice Center under Contract No. 290 2007 10056 I). Rockville, MD: Agency for Healthcare Research and Quality. Retrieved September 26, 2012, from http://www.ncbi.nlm.nih.gov/books/NBK56132/

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Acute Otitis Media (AOM) is a viral and/or bacterial infection of the middle ear and represents the most common childhood infection for which antibiotics are prescribed in the United States. A diagnosis of AOM requires 1) a history of acute onset of signs and symptoms, 2) the presence of middle ear effusion, and 3) signs and symptoms of middle-ear inflammation. There is a high rate of spontaneous resolution for AOM, but if left untreated it can occasionally lead to complications such as acute mastoiditis. The optimal duration of antibiotic therapy is not known and varies worldwide from none to 10 days. One recent strategy is to delay antibiotic treatment until symptoms persist or worsen after several days. Recurrent AOM is generally defined as three episodes in the previous six months or four episodes in the prior year, and has been treated with prophylactic antibiotics or pressure equalization tubes (PE tubes).

Evidence Review

Prevention of AOM in patients with recurrent OM – Medical therapy

The AHRQ review was unable to reach definitive conclusions regarding the comparative effectiveness of different antibiotics for AOM in children with recurrent otitis media. For recurrent otitis media, authors relied on an earlier version of the Leach systematic review to conclude that long-term antibiotic administration was found to decrease AOM episodes from 3 to 1.5 for every 12 months of treatment per otitis prone child during active treatment. The authors caution that the potential consequences of long-term treatment need to be considered.

A Cochrane review (Leach 2011) included 17 studies of children at increased risk of AOM. In seven of these, increased risk was defined as three episodes of AOM in the previous six months or four episodes in the previous year. The other studies defined high risk in a variety of ways, but most included prior episodes of AOM. All excluded children with immunodeficiency or craniofacial abnormalities. In this meta-analysis, long-term antibiotics reduced any episode of AOM and the number of episodes of AOM, with approximately five children needing to be treated long-term to prevent one child experiencing AOM. Antibiotics prevented 1.5 episodes of AOM for every 12 months of treatment per child. Long-term antibiotics were not associated with a significant increase in adverse events.

Prevention of AOM in patients with recurrent OM – Surgical therapy

The Cochrane systematic review addressed the effectiveness of tympanostomy tubes in children with recurrent acute otitis media (defined as three or more acute infections in six months, or four or more acute infections in a year). It included only two randomized controlled trials (RCTs) with a total of 176 children (McDonald 2008). Both trials included children under age three who had a history of at least three episodes of AOM in the six months prior to referral. In one trial, the control was no treatment and in the other, it was daily sulfamethoxazole/trimethoprim syrup at 12mg/kg/day. Both trials reported results categorically as “no episodes of AOM” or “one or more episodes of AOM”, and both found that PE tubes reduce the occurrence of AOM at a follow up of six months, with the larger trial that used a no-treatment control reaching statistical significance. There was no follow up in either trial longer than six months, nor were any harms reported.

The AHRQ report included five RCTs that addressed adenoidectomy, with or without tonsillectomy or tympanostomy. One trial compared adenoidectomy to sulfafurazole and found no significant difference, although the trend was toward favoring the drug. Two trials compared adenoidectomy to placebo, and while both favored the procedure,

neither reached statistical significance. The same was true for the trial that compared adenotonsillectomy to adenoidectomy alone; the trend favored adenotonsillectomy, but results did not reach statistical significance. When adenotonsillectomy was compared to placebo, there was 15% improvement in success rate (defined as no AOM episodes for one year), but given the wide confidence interval, this did not meet the required minimum clinically important difference of 5% adopted by the authors. Lastly, one trial compared adenoidectomy plus PE tubes to PE tubes alone, and found no difference between groups in number of episodes of AOM in the following year. Differences in harms, when reported, were either inconclusive or equivalent.

Overall Summary

For recurrent AOM, prophylactic antibiotics modestly decrease the number of episodes of AOM, with a number needed to treat of five. Pressure equalization tubes may reduce the frequency of acute otitis media in the short-term. Adenoidectomy does not result in a clinically significant decrease in the frequency of AOM.

PROCEDURE

Placement of pressure equalization tubes
Antibiotic Pharmacotherapy
Adenoidectomy
Adenotonsillectomy

DIAGNOSES

Acute otitis media
Recurrent acute otitis media

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
381.0	Acute nonsuppurative otitis media
381.00	… unspecified
381.01	Acute serous otitis media
381.02	Acute mucoid otitis media
381.03	Acute sanguinous otitis media
381.04	Acute allergic serous otitis media
381.05	Acute allergic mucoid otitis media
381.06	Acute allergic sanguinous otitis media
381.4	Nonsuppurative otitis media, not specified as acute or chronic
382.0	Acute suppurative otitis media

CODES	DESCRIPTION
382.00	… without spontaneous rupture of eardrum
382.01	… with spontaneous rupture of eardrum
382.02	… in diseases classified elsewhere
382.4	Unspecified suppurative otitis media
382.9	Unspecified otitis media
315.34	Speech and language developmental delay due to hearing loss
389.00	Conductive hearing loss unspecified
389.03	Conductive hearing loss middle ear
389.05	Conductive hearing loss unilateral
389.06	Conductive hearing loss bilateral
389.08	Conductive hearing loss of combined types
389.2	Mixed conductive and sensorineural hearing loss
389.20	Mixed hearing loss, unspecified
389.21	Mixed hearing loss, unilateral
389.22	Mixed hearing loss, bilateral
389.9	Unspecified hearing loss
ICD-9 Volume 3 (Procedure Codes)	
None	
CPT Codes	
42820	Tonsillectomy and adenoidectomy; younger than age 12
42821	Tonsillectomy and adenoidectomy; age 12 and over
42830	Adenoidectomy, primary; younger than age 12
42831	Adenoidectomy, primary; age 12 and over
42835	Adenoidectomy, secondary; younger than age 12
42836	Adenoidectomy, secondary; age 12 and over
69433	Tympanostomy (requiring insertion of ventilating tube, local or topical anesthesia)
69436	Tympanostomy (requiring insertion of ventilating tube, general anesthesia)
69424	Ventilating tube removal requiring general anesthesia
HCPCS Codes	
None	

Note: Inclusion on this list does not guarantee coverage

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HERC Coverage Guidance – Management of Recurrent Acute Otitis Media in Children
Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
	1	No public comments were received for this topic.	

Routine Cervical Cancer Screening CG Issue Summary

Question: How should the Coverage Guidance *Routine Cervical Cancer Screening* be applied within the Prioritized List?

Question source: Evidence-based Guideline Subcommittee

Issue: Currently cervical cancer screening is covered on the Prevention Lines and through the Diagnostic File without limitations. The Coverage Guidance proposes evidence-based optimal screening intervals. A guideline is necessary to modify the Current Prioritized List coverage of routine cervical cancer screening.

Current Prioritized List Status:

Lines

3 PREVENTIVE SERVICES, BIRTH TO 10 YEARS OF AGE
4 PREVENTIVE SERVICES, OVER AGE OF 10
31 DYSPLASIA OF CERVIX AND CERVICAL CARCINOMA IN SITU, CERVICAL CONDYLOMA
644 OTHER VIRAL INFECTIONS, EXCLUDING PNEUMONIA DUE TO RESPIRATORY SYNCYTIAL VIRUS IN PERSONS UNDER AGE 3

Codes

CODES	DESCRIPTION	
ICD-9 Diagnosis Codes		**Current Lines**
V70.0	Routine general medical examination at a health care facility	4
V72.31	Routine gynecological examination	4
V72.32	Encounter for Papanicolaou cervical smear to confirm findings of recent normal smear following initial abnormal smear	4
V76.2	Special screening for malignant neoplasms; cervix	4
V73.81	Special screening for viral and chlamydial diseases; human papilloma virus	3,4
079.4	Viral and chlamydial infection in conditions classified elsewhere; HPV	644
795.0	Abnormal PAP smear of cervix and cervical HPV	31
CPT Codes		
88141	Cytopathology, cervical or vaginal, requiring interpretation by physician	Diagnostic File
88142-	Cytopathology, cervical or vaginal,	Diagnostic File

CODES	DESCRIPTION	
3	collected in preservative fluid, manual screening	
88147-8	Cytopathology smears, cervical or vaginal	Diagnostic File
88150-4	Cytopathology slides, cervical or vaginal	Diagnostic File
88164-7	Cytopathology slides, cervical or vaginal, Bethesda system	Diagnostic File
88174-5	Cytopathology, cervical or vaginal, collected in preservative fluid, automated screening	Diagnostic File
87620	Detection infectious agent by probe technique; HPV, direct	Diagnostic File
87621	Detection infectious agent by probe technique; HPV, amplified	Diagnostic File
HCPCS Codes		
G0123-4	Screening cytopathology, cervical or vaginal, collected in preservative fluid, automated thin-layer prep	Diagnostic File
G0141	Screening cytopathology, cervical or vaginal, requiring interpretation by physician	Diagnostic File
G0143-5	Screening cytopathology, cervical or vaginal, collected in preservative fluid, automated thin-layer prep	Diagnostic File
G0147-8	Screening cytopathology smears, cervical or vaginal	Diagnostic File

Coverage guidance box:

HERC COVERAGE GUIDANCE

Cervical cancer screening is recommended for coverage in women 21 to 29 years old with cytology alone, every 3 years

- HPV testing with or without cytology is not recommended for coverage

Cervical cancer screening is recommended for coverage in women 30 to 65 years old either with:

- Co-testing every 5 years
- Cytology alone every 3 years

Cervical cancer screening is recommended for coverage in women over 65 years old

- Until adequate screening is achieved*

- Until 20 years after regression or appropriate management of a high-grade precancerous lesion

Cervical cancer screening is not recommended for coverage for the following populations:

- Women less than age 21
- Women who have had a hysterectomy with removal of cervix for non-cervical cancer related reasons (i.e. other than high grade precancerous lesion, CIN 2 or 3, or cervical cancer)
- Women over age 65 who have had adequate prior screening and are not otherwise at high risk of cervical cancer

Specific testing considerations:

- Either liquid based cytology or conventional cytology are appropriate and are recommended for coverage.
- HPV testing is not recommended for coverage for further triaging when low-grade squamous intraepithelial lesions or higher are diagnosed
- The above recommendations also apply to women who have had abnormal testing but whom are indicated to resume routine screening.**

** Adequate screening is defined as 3 consecutive negative cytology results or 2 consecutive negative HPV results within 10 years of the cessation of screening, with the most recent test occurring within 5 years.*

*** Management of abnormal cytology and HPV testing is not addressed in this coverage guidance. The United States Preventive Services Task Force refers to the American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology guideline (Saslow 2012) to address management of abnormal results.*

Note: This guidance does not apply to women who have received a diagnosis of a high-grade precancerous cervical lesion or cervical cancer, women with in utero exposure to diethylstilbestrol, or women who are immunocompromised (such as those who are HIV positive).

HERC Staff Recommendations:

1) Adopt a new guideline

Guideline Note XXX Routine Cervical Cancer Screening

Line 4

Cervical cancer screening is covered on Line 4 for women:

Age group in years	Type of screening covered	Frequency
<21	None	Never
21-29	Cytology alone Mandatory HPV testing (87620-87621) is not covered for women age 21-29	Every 3 years
30-65	Co-testing or cytology alone	Co-testing every 5 years Cytology alone every 3 years
>65	None Unless adequate screening* has not been achieved, or it is <20 years after regression or appropriate management of a high-grade precancerous lesion	Never
Women who have had a hysterectomy with removal of cervix for non-cervical cancer related reasons (i.e. other than high grade precancerous lesion, CIN 2 or 3, or cervical cancer)	None	Never

** Adequate screening is defined as 3 consecutive negative cytology results or 2 consecutive negative HPV results within 10 years of the cessation of screening, with the most recent test occurring within 5 years.*

Women who have received a diagnosis of a high-grade precancerous cervical lesion or cervical cancer, women with in utero exposure to diethylstilbestrol, or women who are immunocompromised (such as those who are HIV positive) are intended to have screening more frequently than delineated in this guideline.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: ROUTINE CERVICAL CANCER SCREENING

DRAFT AS REFERRED BY EBGS TO VBBS ON 2/7/2013

HERC COVERAGE GUIDANCE

Cervical cancer screening is recommended for coverage in women 21 to 29 years old with cytology alone, every 3 years

- HPV testing with or without cytology is not recommended for coverage

Cervical cancer screening is recommended for coverage in women 30 to 65 years old either with:

- Co-testing every 5 years
- Cytology alone every 3 years

Cervical cancer screening is recommended for coverage in women over 65 years old

- Until adequate screening is achieved*
- Until 20 years after regression or appropriate management of a high-grade precancerous lesion

Cervical cancer screening is not recommended for coverage for the following populations:

- Women less than age 21
- Women who have had a hysterectomy with removal of cervix for non-cervical cancer related reasons (i.e. other than high grade precancerous lesion, CIN 2 or 3, or cervical cancer)
- Women over age 65 who have had adequate prior screening and are not otherwise at high risk of cervical cancer

Specific testing considerations:

- Either liquid based cytology or conventional cytology are appropriate and are recommended for coverage.
- HPV testing is not recommended for coverage for further triaging when low-grade squamous intraepithelial lesions or higher are diagnosed
- The above recommendations also apply to women who have had abnormal testing but whom are indicated to resume routine screening.**

** Adequate screening is defined as 3 consecutive negative cytology results or 2 consecutive negative HPV results within 10 years of the cessation of screening, with the most recent test occurring within 5 years.*

*** Management of abnormal cytology and HPV testing is not addressed in this coverage guidance. The United States Preventive Services Task Force refers to the American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology guideline (Saslow 2012) to address management of abnormal results.*

Note: This guidance does not apply to women who have received a diagnosis of a high-grade precancerous cervical lesion or cervical cancer, women with in utero exposure to diethylstilbestrol, or women who are immunocompromised (such as those who are HIV positive).

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
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Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCES

Hartmann, K.E., Hall, S.A., Nanda, K., et al. (2002). *Screening for cervical cancer* [Internet]. Rockville, MD: Agency for Healthcare Research and Quality (US). Retrieved September 18, 2012, from http://www.ncbi.nlm.nih.gov/books/NBK42831/

Moyer, V.A., & U.S. Preventive Services Task Force. (2012). Screening for cervical cancer: US Preventive Services Task Force recommendation statement. *Annals of Internal Medicine, 156*, 880-891.

Saslow, D., Solomon, D., Lawson, H.W., Killackey, M., Kulasingam, S.L., Cain, J., et al. (2012). American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. *CA: A Cancer Journal for Clinicians, 62*(3), 147-172. doi: 10.3322/caac.21139. Retrieved October 8, 2012, from http://www.ncbi.nlm.nih.gov/pubmed/22422631

Vesco, K.K., Whitlock, E.P., Eder, M., Lin, J., Burda, B.U., Senger, C.A., et al. (2011). *Screening for cervical cancer: A systematic evidence review for the U.S. Preventive Services Task Force.* Evidence Synthesis No. 86. AHRQ Publication No. 11-05156-EF-1. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved September 18, 2012, from http://www.ncbi.nlm.nih.gov/books/NBK66099/

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Cervical cancer remains a significant public health issue, even though the incidence and associated mortality of cervical cancer have continued to decrease in the United States since the introduction of cervical cytology screening programs in the 1950s and 60s. In 1950, the Centers for Disease Control (CDC) – Vital Statistics of the United States reported a death rate of 10.2 per 100,000 for white women, while in 2007 the mortality rate had dropped to 2.2. Incidence varies significantly by age and race/ethnicity.

Cervical cancer does not develop suddenly and is preceded by precancerous changes of the cervix. Precancerous changes of the cervix are histologically defined as cervical intraepithelial neoplasia (CIN) and are identified at varying levels of severity: CIN1, CIN2, and CIN3. The latter includes carcinoma in situ. Progression of neoplasia to invasive cervical cancer is slow. The rate of progression of CIN3 to cancer has recently been estimated as 31.3% in 30 years.

It is well recognized that infection with oncogenic human papilloma virus (HPV) is a necessary, although not sufficient, cause of virtually all cervical cancer. While there are multiple types of HPV, types 16 and 18 alone are responsible for approximately 70% of cervical cancer cases, and HPV is present in 99.7% of cases. The progression from HPV infection to cervical cancer occurs over a series of four steps: 1) HPV transmission, 2) acute HPV infection, 3) persistent HPV infection leading to precancerous changes, and 4) invasive cervical cancer. A high proportion of sexually active women become infected with HPV, but only a small proportion of HPV infections become persistent. Among 4,504 women aged 18 years and older with a cytologic diagnosis of atypical squamous cells of uncertain significance or low-grade squamous intraepithelial lesion, 91% of prevalent HPV infections detected at enrollment cleared within 24 months. These data illustrate that HPV infections are very likely to regress, and persistence of HPV infection is more likely to occur in older women. Numerous analyses, including large cohort studies, have demonstrated that CIN not only progresses, but may also regress. Newer data suggest that CIN1 does not predict any meaningful risk of CIN3.

While it is estimated that around 80% of US women have had cervical cytology screening within the past three years, screening history varies by educational attainment, race/ethnicity, and age. While the great majority of US women have had recent cytology screening, the majority of cervical cancer cases occur in those without such a history.

With regard to screening methods, liquid-based cytology differs from conventional cytology in how the cervical specimen is sent to the cytology laboratory for evaluation. For conventional cytology, the cervical specimen is smeared onto a glass slide immediately after collection and the slide is either sprayed with or placed in fixative. For liquid-based cytology, the sample collected from the cervix is suspended in fixative, then collected by filtration on a membrane, and then transferred onto a microscope slide in a monolayer.

In recent years, high-risk HPV testing has been incorporated into screening and screening triage algorithms, as either a combined test (with cytology, co-test) to determine rescreening interval in women who are cytology negative, or as one possible triage strategy to determine colposcopy. There are many methods available for detecting HPV, including in situ hybridization, polymerase chain reaction, and Hybrid Capture (HC2) technology.

Evidence Review

US Preventive Services Task Force Clinical Considerations

Patient Population under Consideration

This recommendation statement applies to all women who have a cervix, regardless of sexual history. This recommendation statement does not apply to women who have received a diagnosis of a high-grade precancerous cervical lesion or cervical cancer, women with in utero exposure to diethylstilbestrol, or women who are immunocompromised (such as those who are HIV positive).

Screening Tests

The effectiveness of cervical cancer screening observed in the United States over the past several decades is attributed to the use of conventional cytology. Current evidence indicates that there are no clinically important differences between liquid-based cytology and conventional cytology. The USPSTF realizes that the choice of cytology method may not be under the direct control of the clinician and considers cytology screening in appropriate age groups at appropriate intervals to be of substantial net benefit, regardless of method. Human papillomavirus testing with Digene Hybrid Capture 2 (HC2) (Qiagen, Germantown, Maryland) is commonly used in the United States, and both HC2 and polymerase chain reaction– based methods have been evaluated in effectiveness trials. Although alternative HPV detection methods are emerging, the clinical comparability and implications of these methods are not completely understood.

Screening Interval

Screening women aged 21 to 65 years every 3 years with cytology provides a reasonable balance between benefits and harms. Among women aged 30 to 65 years, HPV testing combined with cytology (co-testing) every 5 years offers a comparable balance of benefits and harms and is therefore a reasonable alternative for women in this age group who would prefer to extend the screening interval. Screening with cytology more often than every 3 years confers little additional benefit, with large increases in harms, including additional procedures and assessment and treatment of transient lesions. Treatment of lesions that would otherwise resolve on their own is harmful because it can lead to procedures with unwanted side effects, including the potential for cervical incompetence and preterm labor. Similarly, HPV testing with cytology should not be done more often than every 5 years to maintain a reasonable balance of benefits and harms similar to that seen with cytology alone every 3 years. Among women younger than 30 years, there is adequate evidence that screening with HPV testing (alone or in combination with cytology) confers little to no benefit, and that the harms of HPV testing in this age group are moderate. Therefore, routine screening with HPV in this population is not recommended.

Maintaining the comparability of the benefits and harms of co-testing and cytology alone demands that patients, clinicians, and health care organizations adhere to currently recommended screening intervals, protocols for repeated testing, cytologic thresholds for further diagnostic testing (that is, colposcopy) and treatments, and extended surveillance as recommended by current American Cancer Society/American Society for Colposcopy and Cervical Pathology/American Society for Clinical Pathology (ACS/ASCCP/ASCP) guidelines. Women who choose co-testing to increase their screening interval (and potentially decrease testing) should be aware that positive screening results are more likely with HPV-based strategies than with cytology alone and that some women may require prolonged surveillance with additional frequent testing if they have persistently positive HPV results. Because HPV test results may be positive among women who would otherwise be advised to end screening at age 65 years on the basis of previously normal cytology results alone, the likelihood of continued testing may increase with HPV testing. The percentage of US women undergoing co-testing who will have a normal cytology test result and a positive HPV test result (and who will therefore require additional testing) ranges from 11% among women aged 30 to 34 years to 2.6% among women aged 60 to 65 years.

Triage of Women with Atypical Squamous Cells of Uncertain Significance

For the triage of women with atypical squamous cells of uncertain significance cytology to colposcopy, a single HC2 test has a higher sensitivity and similar specificity compared to single repeat cytology at a threshold of atypical squamous cells of uncertain significance for the detection of CIN2+. No additional benefit occurs when HC2 triage is combined with cytology, but this strategy increases false positives. The HC2 does not appear useful for the triage of women with low-grade squamous intraepithelial lesion cytology because such a high proportion of women will test positive. Human papilloma virus testing has few unique harms compared with cytology screening, but a positive HPV test may increase anxiety and distress, in the short-term only.

Timing of Screening

Women Younger Than Age 21 Years

Cervical cancer is rare before age 21 years. The USPSTF found little evidence to determine whether and how sexual history should affect the age at which to begin screening. Although exposure of cervical cells to sexually transmitted HPV during vaginal intercourse may lead to cervical carcinogenesis, the process has multiple steps, involves regression, and is generally not rapid. There is evidence that screening earlier than age 21 years, regardless of sexual history, would lead to more harm than benefit. The harms are greater in this younger age group because abnormal test results are likely to be transient and to resolve on their own; in addition, treatment may have an adverse effect on childbearing.

Women Older Than Age 65 Years
Clinicians and patients should base the decision to end screening on whether the patient meets the criteria for adequate prior testing and appropriate follow-up per established guidelines. The ACS/ASCCP/ASCP guidelines define adequate prior screening as 3 consecutive negative cytology results or 2 consecutive negative HPV results within 10 years before cessation of screening, with the most recent test occurring within 5 years. They further state that routine screening should continue for at least 20 years after spontaneous regression or appropriate management of a high-grade precancerous lesion, even if this extends screening past age 65 years. The ACS further states that screening should not resume after cessation in women older than age 65 years, even if a woman reports having a new sexual partner.

Women Older Than Age 65 Years Who Have Never Been Screened
Screening may be clinically indicated in older women for whom the adequacy of prior screening cannot be accurately accessed or documented. Women with limited access to care, minority women, and women from countries where screening is not available may be less likely to meet the criteria for adequate prior screening. The USPSTF realizes that certain considerations may support screening in women older than age 65 years who are otherwise considered high risk (such as women with a high grade precancerous lesion or cervical cancer, women with in utero exposure to diethylstilbestrol, or women who are immunocompromised).

Assessment of Risk
It is well-established that HPV infection is associated with nearly all cases of cervical cancer. Other risk factors include HIV infection, a compromised immune system, in utero exposure to diethylstilbestrol, and previous treatment of a high-grade precancerous lesion or cervical cancer. Women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion or cervical cancer are not at risk for cervical cancer and should not be screened. Women who had their cervix removed during surgery for ovarian or endometrial cancer are not at high risk for cervical cancer and would not benefit from screening. Clinicians should confirm through review of surgical records or direct examination that the cervix was removed.

Recommendations

These recommendations apply to women who have a cervix, regardless of sexual history. These recommendations do not apply to women who have received a diagnosis of a high-grade precancerous cervical lesion or cervical cancer, women with in utero exposure to diethylstilbestrol, or women who are immunocompromised (such as those who are HIV positive).

- The USPSTF recommends screening for cervical cancer in women ages 21 to 65 years with cytology (Pap smear) every 3 years or, for women ages 30 to 65 years who want to lengthen the screening interval, screening with a combination of cytology and human papillomavirus (HPV) testing every 5 years. Grade: A Recommendation.

- The USPSTF recommends against screening for cervical cancer in women younger than age 21 years. Grade: D Recommendation.
- The USPSTF recommends against screening for cervical cancer in women older than age 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer. Grade: D Recommendation.
- The USPSTF recommends against screening for cervical cancer in women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer. Grade: D Recommendation.
- The USPSTF recommends against screening for cervical cancer with HPV testing, alone or in combination with cytology, in women younger than age 30 years. Grade: D Recommendation.

Overall Summary

A reasonable age at which to initiate cervical cancer screening in women is age 21. For cytology-based screening, liquid-based cytology does not differ from conventional cytology in sensitivity, specificity, or relative CIN detection. Screening women aged 21 to 65 years every 3 years with cytology provides a reasonable balance between benefits and harms. Among women aged 30 to 65 years, HPV testing combined with cytology (co-testing) every 5 years offers a comparable balance of benefits and harms. Screening with cytology more often than every 3 years confers little additional benefit, with large increases in harms. Among women younger than 30 years, screening with HPV testing (alone or in combination with cytology) confers little to no benefit but has moderate harms. Treatment of lesions that would otherwise resolve on their own is harmful because it can lead to procedures with unwanted side effects, including the potential for cervical incompetence and preterm labor. For the triage of women with atypical squamous cells of uncertain significance cytology to colposcopy, a single HC2 test has a higher sensitivity and similar specificity compared to single repeat cytology, but there are no additional benefits when HC2 triage is combined with cytology. The HC2 is not useful for the triage of women with low-grade squamous intraepithelial lesion cytology. It is reasonable to discontinue routine cervical cancer screening for women older than age 65 years who have had adequate screening with negative results and who are not otherwise at high risk for cervical cancer, and for women who have undergone a hysterectomy in which the cervix was removed, unless it was performed because of cervical cancer.

SUBCOMMITTEE DELIBERATIONS

The Evidence-based Guidelines Subcommittee decided to issue coverage guidances that reflects the optimal intervals of cervical cancer screening. They discussed some concerns about whether specific language about intervals would be overly restrictive, such as in the case when a woman presents to a provider's office a few weeks or months before her screening is due. After consideration, the subcommittee decided to express the desired target interval for screening and to leave such implementation considerations to health plans.

PROCEDURE

Pap smear
HPV testing

DIAGNOSES

Cervical cancer screening

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
V76.2	Special screening for malignant neoplasms; cervix
V73.81	Special screening for viral and chlamydial diseases; human papilloma virus
079.4	Viral and chlamydial infection in conditions classified elsewhere; HPV
795.0	Abnormal PAP smear of cervix and cervical HPV
V70.0	Routine general medical examination at a health care facility
V72.31	Routine gynecological examination
V72.32	Encounter for Papanicolaou cervical smear to confirm findings of recent normal smear following initial abnormal smear
ICD-9 Volume 3 (Procedure Codes)	
None	
CPT Codes	
88141	Cytopathology, cervical or vaginal, requiring interpretation by physician
88142-3	Cytopathology, cervical or vaginal, collected in preservative fluid, manual screening
88147-8	Cytopathology smears, cervical or vaginal
88150-4	Cytopathology slides, cervical or vaginal
88164-7	Cytopathology slides, cervical or vaginal, Bethesda system
88174-5	Cytopathology, cervical or vaginal, collected in preservative fluid, automated screening
87620	Detection infectious agent by probe technique; HPV, direct
87621	Detection infectious agent by probe technique; HPV, amplified
HCPCS Codes	
G0123-4	Screening cytopathology, cervical or vaginal, collected in preservative fluid, automated thin-layer prep
G0141	Screening cytopathology, cervical or vaginal, requiring interpretation by physician
G0143-5	Screening cytopathology, cervical or vaginal, collected in preservative fluid, automated thin-layer prep
G0147-8	Screening cytopathology smears, cervical or vaginal

Note: Inclusion on this list does not guarantee coverage

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

HERC Coverage Guidance – Cervical Cancer Screening
Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
American Cancer Society Cancer Action Network Portland, OR	1	The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy partner of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As such, we support the Health Evidence Review Commission's proposed coverage guidance for cervical cancer screening.	Thank you for taking the time to comment.
	2	The recommendations put forth by the Evidenced-based Guidelines Subcommittee are very similar to the American Cancer Society's guidelines which I've included below: • All women should begin cervical cancer screening at age 21 • Women between the ages of 21 and 29 should have a Pap test every 3 years. They should not be tested for HPV unless it is needed after an abnormal Pap test result • Women between the ages of 30 and 65 should have both a Pap test and an HPV test every 5 years. This is the preferred approach, but it is also OK to have a Pap test alone every 3 years • Women over age 65 who have had regular screenings with normal results should not be screened for cervical cancer. Women who have been diagnosed with cervical pre-cancer should continue to be screened • Women who have had their uterus and cervix removed in a hysterectomy and have no history of cervical cancer or pre-cancer should not be screened • Women who have had the HPV vaccine should still follow the screening recommendations for their age group • Women who are at high risk for cervical cancer may need to be screened more often. Women at high risk might include those with HIV infection, organ transplant, or exposure to the drug DES. They should talk with their doctor or nurse	Thank you for providing this information.
	3	In 2012, it is estimated that 130 women will be diagnosed with cervical cancer in Oregon[1]. It is well known that finding the disease at an early stage increases the opportunity for effective treatment and patient survival and we are pleased to see effective preventative and early detection measures being recommended by this committee. Thank you for your time and consideration on this important issue.	Thank you for your comment.

CG - Coronary Artery Calcium Scoring

Question: How should the coverage guidance on Coronary Artery Calcium Scoring be applied to the Prioritized List?

Question source: Evidence-based Guideline Subcommittee

HERC Coverage Guidance
Coronary artery calcium scoring (CACS) should not be covered.

Current Prioritized List status:

Code	Description	List placement
75571	Computed tomography of heart, without contrast, with qualitative evaluation of coronary calcium	Excluded File

HERC Staff Recommendations:
No change is necessary to the Prioritized List

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: CORONARY ARTERY CALCIUM SCORING

DRAFT FOR VBBS/HERC MEETING MATERIALS 3/14/2013

HERC COVERAGE GUIDANCE

Coronary artery calcium scoring (CACS) should not be covered.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCES

Hayes, Inc. (2012). *Coronary artery calcium scoring to assess the risk of coronary artery disease in asymptomatic adults.* Lansdale, PA: Hayes, Inc.

National Institute for Health and Clinical Excellence (NICE). (2010). *Chest pain of recent onset: Assessment and diagnosis of recent onset chest pain or discomfort of suspected cardiac origin.* London: NICE. Retrieved August 31, 2012, from http://www.nice.org.uk/nicemedia/live/12947/47938/47938.pdf

U.S. Preventive Services Task Force. (2009). Using Nontraditional Risk Factors in Coronary Heart Disease Risk Assessment 2009. Retrieved August 31, 2012, from http://www.uspreventiveservicestaskforce.org/uspstf09/riskcoronaryhd/coronaryhdrs.htm

Washington State Health Care Authority Health Technology Assessment Program. (2009). *Coronary artery calcium scoring (CACS) as a diagnostic test for detection of coronary artery disease.* Olympia, WA: Health Technology Assessment Program. Retrieved August 31, 2012, from http://www.hta.hca.wa.gov/calscoring.html

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

Clinical Background

Coronary artery calcification is part of the development of atherosclerosis. It is an active process that begins as early as the second decade of life and occurs exclusively in atherosclerotic arteries and is absent in the normal vessel wall. A close relationship has been confirmed between the extent of coronary artery calcification and the atherosclerotic plaque burden seen in coronary artery disease (CAD), making calcium a potential marker for diseased arteries.

Coronary calcification is pervasive in patients with confirmed CAD and increases with age. Increasing prevalence of coronary artery calcified plaque parallels the increasing prevalence of coronary atherosclerosis over the lifespan. However, the presence of calcified coronary plaque is not strongly correlated with the extent of histopathologic stenosis. The inner lining of both obstructed and non-obstructed vessels contains coronary artery calcified plaque; therefore, the detection of calcified plaque on cardiac CT is not specific to an obstructive lesion.

Currently, the most common method for determining coronary artery calcium (CAC) score use computed tomography (CT), either electron beam CT or multidetector CT for the detection and quantification of the amount of coronary artery calcium. However, calcification in vessels may be present in both obstructive and nonobstructive lesions and thus, coronary artery calcium is not specific for obstructive CAD.

The role of coronary artery calcium scoring (CACS) as a diagnostic or clinical decision-making tool in symptomatic persons has not been well defined. It is not likely to be a replacement for conventional coronary angiography, which is the gold standard anatomical test for CAD. Some proponents of CACS suggest that it may be most useful in separating persons who are unlikely to have significant coronary artery obstruction from those who should be referred for additional diagnostic testing. From this perspective, those with little or no calcium are less likely to have CAD requiring further evaluation, hospitalization or intervention. Those with a positive CACS are then often referred for stress tests to evaluate myocardial function, perfusion studies and/or invasive conventional coronary angiography and appropriate treatment.

In clinical practice, CACS may be used to determine whether patients presenting with chest pain should have further testing. Coronary artery calcium scoring as a stand-alone diagnostic test, however, is less common. (The more common use appears to be the evaluation of asymptomatic patients.) Coronary artery calcium scoring is increasingly performed in conjunction with CT coronary angiography using multidetector CT.

Electron beam CT and multidetector CT, both used for CACS, expose the patient to ionizing radiation. Potential adverse health effects associated with radiation exposure may be of concern to patients as well as clinicians. Presumably patients with a positive CACS may also have other diagnostic tests that involve ionizing radiation. Thus, radiation exposure related to CACS should be put in the context of additional testing that may be indicated.

Evidence Review

US Preventive Services Task Force Report on Using Nontraditional Risk Factors in Coronary Heart Disease Risk Assessment

The report pertains only to asymptomatic patients, and makes the following recommendations:

Clinicians should use the Framingham model to assess coronary heart disease (CHD) risk and to guide risk-based therapy until further evidence is obtained. Because adding nontraditional risk factors (including CACS) to CHD assessment requires additional patient and clinical staff time and effort, routinely screening with nontraditional risk factors could result in lost opportunities for provision of other important health services of proven benefit.

This recommendation is to be used for those who fall into a 10% to 20% (intermediate) 10-year risk category after being screened for CHD risk by using traditional CHD risk factors. Using a risk assessment tool is a key step in managing CHD risk in patients. One validated method of assessing CHD risk is the Framingham model. Persons with low (<10%) Framingham risk scores do not benefit from aggressive risk factor modification, whereas those with high (>20%) Framingham risk scores do benefit. Examples of persons who fall into the intermediate-risk category include a 60-year-old male smoker with untreated hypertension or a 60-year-old female with untreated hypertension and hyperlipidemia. The current recommendation used the Adult Treatment Panel III Framingham risk calculator (available at http://hp2010.nhlbihin.net/atpiii/calculator.asp?usertype.prof) and does not include diabetic populations.

The USPSTF found no evidence that risk stratification with any nontraditional risk factors including CACS, either independently or in addition to Framingham risk scoring, reduces myocardial infarction or cardiovascular disease mortality compared with risk stratification and treatment on the basis of Framingham scoring alone. Therefore, the USPSTF examined the evidence for the independent and additive predictive value of each nontraditional risk factor in assessing 10-year risk for myocardial infarction and CHD mortality. For those risk factors for which evidence for independent or additive

predictive value is available, the USPSTF evaluated the evidence for the effect such factors may have on recategorizing intermediate-risk persons into low- or high-risk groups.

Regarding CACS, the evidence review found poor- to fair-quality evidence indicating that higher CAC scores on electron beam CT predict CHD events independent of Framingham risk factors, on the basis of a systematic review of eight cohort studies. Three good-quality population cohort studies and five fair-quality studies reported that the highest CAC score groups had significantly greater relative risk estimates than the lowest score groups. Although three of the studies met the technical requirements for a good-quality rating, none of them make a convincing case that CAC adds information about intermediate-risk persons. One of the three included only low-risk persons. Another study, from the Rotterdam Coronary Calcification Study, used self-selected participants who were classified into two categories (10-year Framingham risk of >20% or <20%), and results for the intermediate-risk group (10% to 20%) were therefore not reported separately. Several features of the third study, from the South Bay Heart Watch, limit its applicability to an intermediate risk group. The predictive value of a high CAC score was inconsistent; for example, participants with a Framingham risk score of 11% to 15% and participants with a risk score of 16% to 20% had the same baseline risk (7%). The CAC score also seemed to be imprecise; among participants who had a high CAC score, those with a pretest Framingham risk score of 10% to 15% had a higher posttest risk (19%) than those with a pretest score of 16% to 20%. Finally, participants were potentially self-selected. The five studies rated as fair quality were primarily limited by their use of proxy measures to control for Framingham risk factors or their recruitment of self-selected participants.

In summary, although the eight included studies consistently reported statistically significant relative risks for coronary events with increasing CAC scores, no study uniformly met all three of the following conditions: addressed an intermediate-risk cohort, was population-based or free of selection bias, and appropriately measured or controlled for traditional risk factors.

Hayes Report on Use of CACS in Asymptomatic Adults

The available evidence suggests that CACS adds incremental predictive value over traditional risk factor assessments such as the Framingham Risk Score, particularly among asymptomatic adults at intermediate risk of a CAD event. Among three studies, 20% to 55% of those initially classified as intermediate risk were reclassified once CAC scores were considered. However, it is not yet known whether the addition of CACS to standard risk factor assessment will improve patient-important outcomes (i.e., cardiac events). The one randomized trial comparing scanning with conventional risk factor analysis alone reported that CAC scanning was associated with some improvement in clinical risk factors for CAD, but there was no difference in adverse event rate between the scanned and non-scanned groups. Computed tomography-induced radiation exposure is the single biggest safety concern in relation to CACS.

Washington HTA Report (Coronary Artery Calcium Scoring)

The Washington HTA report addresses the use of CACS in symptomatic patients only.

CACS test characteristics
The role of CACS as a diagnostic test is not clear from the literature and there is no consensus on appropriate thresholds for determining a negative versus positive test. It is not likely to be a replacement for conventional coronary angiography based on test performance characteristics. Some literature suggests that it might be used for triaging symptomatic patients (both stable outpatients, and patients with acute chest pain presenting to the emergency department) and that CACS may reduce the use of conventional coronary angiography.

- A CACS > 0 is highly sensitive (99%, CI = 98% - 99%) for identifying the presence of obstructive CAD, however specificity was only 35%.
- At thresholds of CAC scores ≥ 100 (5 studies) or ≥ 400 (3 studies) the sensitivity is lower (85% and 78% respectively) but specificity is improved (77% and 83%, respectively).

Safety of CACS
The primary safety concerns for CACS relate to radiation exposure and the consequences of incidental findings.

- Radiation exposure
  - To date, no large-scale epidemiologic studies evaluating cancer risk associated with CT in general have been published.
  - There is uncertainty and controversy with regard to the actual risk of low dose radiation. Quantification of risk specific to CACS for an individual patient is not possible.
  - A typical effective dose for CACS is estimated to be 3 mSV (reported range 0.7 -12 mSv) when retrospective and prospective gating are considered together. Exposure is less when scans are prospectively gated. Some experts consider the potential for harm from radiation exposure to be clinically significant particularly given that patients may be likely to have additional tests using radiation.
  - A recent simulation estimating radiation dose and cancer risk suggests that a single scan for CACS may increase lifetime cancer risk. For a single screen at 55 years of age, based on a median effective dose of 2.3 mSv, site-specific estimates for lifetime risk of radiation induced cancer suggest that most cases would be lung cancer (6/100,000 in men, 14/100,000 in women) or breast cancer (4/100,000 in women).
  - The extent to which CACS is an adjunct to coronary CT angiography may increase radiation exposure compared with that for CACS alone.
- Consequences of incidental findings
  - Data from two studies suggests that 7% to 10% of symptomatic persons will have incidental findings during a CT scan for calcium scoring that require

further diagnostic testing and a small percent, 1.2%, will require therapeutic intervention. There may be benefits to early detection and treatment of the small percentage of significant pathology found incidentally, however, there is no evidence from these studies that early detection prompted more effective treatment or enhanced patient outcomes.

- The follow-up of less serious findings may create patient anxiety in addition to exposing them to the inconvenience, costs and risks of additional testing.

Influence on clinical decision making and patient outcomes

- There is an association between CACS and future events: Patients with higher CACS may experience more cardiac events (e.g. myocardial infarction, revascularization, death) and those with no calcium or low scores may be less likely to have future events. The extent to which CACS truly influences outcomes is unclear, however, since its impact on clinical decision making and treatment is not described.
- While there are a number of studies describing the potential role of CACS as a triage tool for ruling out CAD and identifying those who should have additional testing, none of the studies included a comparison group. If CACS was a perfectly sensitive test, there were no false negatives and some degree of specificity, the benefit of doing CACS as a first test for triage could be estimated in the absence of an explicit comparison group. Without this or a comparison group, it is difficult to assess the incremental benefit of CACS in clinical decision making.

Special populations

- Two moderate quality validation studies in symptomatic diabetic patients suggest that the sensitivity (98-99%) and specificity (25-39%) of CACS for the detection of any calcium is similar to that for general populations from the meta-analysis of Level of Evidence (LoE) I/II studies but that a higher percent (11-25%) of persons with a negative test would have CAD.
- Three moderate quality (LoE II/III) studies described performance characteristics for men and women separately. At a CACS >0, the sensitivities for both groups were 96%-100%. Specificities for women ranged for 41% to 66% and those for men 24% to 57%, somewhat lower. A higher percent (4-11%) of men with a negative test would have CAD compared with women (0-4%). The prevalence of CAD was lower in women (36-47%) compared with men (53-70%). Women present with CAD at an older age (~10 years) than men, which may account for the differences.
- Seven LoE I/II studies explored the relationship of age with test performance characteristics. The prevalence of CAD and presence of calcium increases with age. There are, however somewhat mixed results regarding the extent to which age influences test performance characteristics. While some studies suggest that sensitivity and predictive values go up with increasing age, others suggest that the best sensitivity and specificity may be in middle aged patients (40-60 years).

Economic implications

- Two full economic studies and one costing evaluate CACS as a stand-alone test compared with conventional angiography.
- The two moderate quality full economic studies suggest that at a disease prevalence of up to 70%, CACS may be more cost effective than conventional angiography, however incremental cost effectiveness is not described.
- Disease prevalence and CAC score cut-off (and corresponding sensitivity and specificity) appear to influence overall cost-effectiveness.
- Models did not include evaluation of incidental findings and the influence of false-negative and false-positive tests is not clear.
- Coronary artery calcium scoring does not appear to function as a stand-alone test in clinical practice. The potential impact of additional testing done in clinical practice needs to be considered and modeled.
- There is insufficient evidence for conclusions on the long-term cost utility of CACS compared with conventional coronary angiography alone or with regard to other non-invasive tests.

WA HTA Clinical Committee Decision

The WA HTA clinical committee decided against coverage of CACS. Their rationale is outlined below:

- The committee agreed with the evidence report and found that CACS sensitivity and reliability are high for CACS, though specificity is low and like other tests, accuracy is affected by the disease prevalence. While accuracy and reliability are critical, they are only a first step as to whether a test is effective. The committee also agreed that there is no evidence to establish a clinically important threshold: increase in calcium does indicate disease, but the correlation to severity of stenosis is not established – which is key in a disease that is widely prevalent, where serious events occur in some, but are difficult to predict.
- In evaluating effectiveness, the most rigorous question is whether substituting this test, instead of a current diagnostic, results in better treatment and outcomes. In this case, the evidence is insufficient and current clinical practice does not support using this test alone or as a substitute.
- The other diagnostic effectiveness key question discussed by the committee is whether there is evidence that using this test as an added tool to current strategy provides a benefit (clinical or cost). The remaining analysis relate to answering this question.
- One potential use would be in ER where symptomatic patient at low to intermediate risk - could rule out disease. This use would require CACS of 0 value, so the specificity goes down, and at least a 5% group would still receive a negative test, but would have disease. One small retrospective study looked at 4 month follow up on 100 patients in ED where CACS score was taken, along with

other tests and concluded that a score of 0 could permit a discharge. CACS studies did not include any RCT or higher quality observational trials to explicitly test what different clinical or treatment choices are made. The clinical expert noted that there is usually a need for a functional test to confirm.

- The committee noted that national guidelines do not endorse the use of CACS, though some have permissive statements for use of the test.

NICE Guideline: Chest Pain of Recent Onset

The NICE guideline does not address the use of CACS in patients presenting with acute chest pain. For patients presenting with stable chest pain in the outpatient setting, they make the following recommendations pertaining to CACS:

> In people without confirmed CAD, in whom stable angina cannot be diagnosed or excluded based on clinical assessment alone, estimate the likelihood of CAD (see Table 1). Take the clinical assessment and the resting 12-lead ECG [electrocardiogram] into account when making the estimate. Arrange further diagnostic testing as follows:
>
> - If the estimated likelihood of CAD is 61–90%, offer invasive coronary angiography as the first-line diagnostic investigation if appropriate.
> - If the estimated likelihood of CAD is 30–60%, offer functional imaging as the first-line diagnostic investigation.
> - If the estimated likelihood of CAD is 10–29%, offer CACS as the first-line diagnostic investigation. If the calcium score is:
>   - zero, consider other causes of chest pain
>   - 1–400, offer 64-slice (or above) CCTA
>   - greater than 400, offer invasive coronary angiography.

Table 1. Percentage of people estimated to have coronary artery disease according to typicality of symptoms, age, sex and risk factors

	Non-anginal chest pain				Atypical angina				Typical angina			
	Men		Women		Men		Women		Men		Women	
Age (years)	Lo	Hi	Lo	Hi	Lo	Hi	Lo	Hi	Lo	Hi	Lo	Hi
35	3	35	1	19	8	59	2	39	30	88	10	78
45	9	47	2	22	21	70	5	43	51	92	20	79
55	23	59	4	25	45	79	10	47	80	95	38	82
65	49	69	9	29	71	86	20	51	93	97	56	84
For men older than 70 with atypical or typical symptoms, assume an estimate > 90%. For women older than 70, assume an estimate of 61–90% EXCEPT women at high risk AND with typical symptoms where a risk of > 90% should be assumed.												
Values are percent of people at each mid-decade age with significant coronary artery disease (CAD)[1]. Hi = High risk = diabetes, smoking and hyperlipidaemia (total cholesterol > 6.47 mmol/litre). Lo = Low risk = none of these three. The shaded area represents people with symptoms of non-anginal chest pain, who would not be investigated for stable angina routinely. Note: These results are likely to overestimate CAD in primary care populations. If there are resting ECG ST-T changes or Q waves, the likelihood of CAD is higher in each cell of the table.												

Discussion of the evidence for CACS in the NICE guideline is as follows:

Advantages and Disadvantages

The main advantages of calcium scoring are that calcium scanning takes approximately five minutes to perform and interpret, there is minimal radiation exposure (1.5 to 3 mSv) compared with multislice coronary angiography, no contrast material is required, the quantification of plaque (calcium score) enables non invasive temporal tracking of atherosclerosis burden and, although not of direct relevance to the investigation of CAD, it detects significant extra-cardiac findings in 2% to 3% as a coincidental finding. The disadvantages include the following; does not assess whether significant coronary stenoses are present, does not make a functional assessment of myocardial ischaemia, and left ventricular function is not assessed. Although coronary artery calcium is well correlated with total plaque volume or atherosclerotic burden it is not a direct marker of the vulnerable plaque at risk of rupture. However, the greater the calcium score the greater the potential for increased numbers of potentially lipid-rich plaques.

Evidence of Diagnostic Efficacy

No systematic reviews were identified. Ten studies were reviewed in total. With increasing thresholds of Agatston calcium score ranges, (from > 0 to 100, and > 100 in 3 studies, and from > 0 to 100, >100 to 400, and > 400 in 3 studies) the sensitivity decreased and the specificity increased for the detection of significant CAD. No evidence was found for the diagnostic accuracy of coronary calcium scores to diagnose significant CAD in ethnic minority groups in the UK. From economic modelling

[1] Adapted from Pryor DB, Shaw L, McCants CB et al. (1993) Value of the history and physical in identifying patients at increased risk for coronary artery disease. *Annals of Internal Medicine 118*(2),81-90.

undertaken for this guideline, there is evidence that for patients with a low pre-test-probability of CAD (<25%), 64-slice CT coronary angiography preceded by testing using calcium scoring is cost-effective compared to functional testing and invasive coronary angiography.

Economic Evaluations
Of the six economic evaluations included in evidence reviewed for this guideline, only one addressed CACS. Rumberger 1999 compared exercise ECG, stress echocardiography (ECHO), stress thallium and CACS. The incremental analysis showed that electron beam CT using a calcium score threshold of >37, >80 or >168 is cost saving compared with stress ECHO and stress thallium testing. At low to moderate disease prevalence (10% to 20%), electron beam CT using thresholds of >37, >80 or >168 are cost saving compared with exercise ECG. Electron beam CT using a threshold of >0 is cost saving compared with stress thallium testing at 20% CAD prevalence and above.

The NICE guideline authors performed their own economic analysis of a diagnostic strategy that incorporated the use of calcium scoring using 64-slice CT coronary angiography as a precursor to full 64-slice CT coronary angiography. This was done as a way of minimizing the risk of radiation from 64- slice CT coronary angiography, a risk which was not explicitly incorporated into the other models. Results of the base case analysis indicate that for lower risk groups (5% and 20%), the use of calcium scoring as a first line testing strategy is likely to be cost-effective and should be followed by either 64-slice CT coronary angiography alone or with additional invasive coronary angiography as a confirmatory 3rd test. In higher risk populations, (CAD prevalence greater than 40%), a strategy of sending all patients directly to invasive coronary angiography is likely to be cost-effective. The model indicates that MPS with SPECT is excluded through dominance or extended dominance at every level of CAD prevalence. It also indicates that exercise ECG is only cost-effective as a first line investigation strategy at 5% CAD prevalence, but that even in this instance replacing exercise ECG with calcium scoring is likely to improve effectiveness at a reasonable level of additional cost.

Overall Summary

There is no evidence that risk stratification in asymptomatic patients using CACS reduces myocardial infarction or cardiovascular disease mortality compared with risk stratification and treatment on the basis of Framingham scoring alone. Coronary artery calcium scoring may have a diagnostic role in the “rule out” of obstructive CAD in emergency department patients with acute chest pain and normal ECGs and initial cardiac enzymes, and in outpatients with stable chest pain with a low probability of obstructive CAD. However, there is little data available to support long-term outcomes using calcium scoring as a strategy, and it does not appear to function as a stand-alone test in clinical practice. The potential impact of radiation exposure, both from the CACS and from additional testing done to confirm the diagnosis or to evaluate incidental findings, needs to be considered, and current studies do not adequately address these concerns. One economic evaluation suggests that the most cost-effective course of

action for stable outpatients with a low probability of CAD (10-29%) is CACS, followed by CCTA if the CACS score is 1-400, or invasive angiography if the score is greater than 400, however, this was from the perspective of the UK National Health Service, and applicability to the US setting is limited given differences in costs and the non-existence of accepted follow up algorithms.

PROCEDURE

Electron beam coronary computed tomography
Multidetector coronary computed tomography
Coronary Artery Calcium Scoring

DIAGNOSES

Coronary artery disease
Chest pain

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
410	Acute myocardial infarction
411	Other acute and subacute forms of ischemic heart disease
413	Angina pectoris
414	Other forms of chronic ischemic heart disease
786.5	Chest pain
ICD-9 Volume 3 (Procedure Codes)	
87.41	Computed axial tomography of the heart
CPT Codes	
75571	Computed tomography of heart, without contrast, with qualitative evaluation of coronary calcium
HCPCS Codes	
None	

Note: Inclusion on this list does not guarantee coverage

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

HERC Coverage Guidance – Coronary Artery Calcium Scoring
Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
Society of Cardiovascular Computed Tomography Vienna, VA	1	It appears that the documents the committee reviewed, while appropriate, under-represented the data available regarding coronary calcium. Below please find some additional information related to the indications addressed. As Medicare and other payers including the California Technology Assessment Forum (Blue Cross/Blue Shield Tech Assessment) have made positive determinations in regarding coronary calcium coverage, we would hope you would consider the following information as supplemental. If it pleases the committee, we would be glad to provide a Professor of Medicine to present the data in a scientific forum to help address the specific questions regarding the science	Thank you for taking the time to comment. Medicare coverage policy as reported in the WA HTA report noted no national coverage decision, and a non-coverage local (Washington) coverage decision. We searched the Medicare Coverage Database and identified no positive coverage decision and one non-coverage local coverage decision from Minnesota. The California Technology Assessment Forum has made determinations on cardiac CT angiography, but we are unable to identify a determination on EBCT or CACS, or a BCBS Technology Assessment on those topics.
	2	Below are some specific comments regarding the document and some additional data. **UK NICE GUIDELINES** The SCCT would like to point out that the UK Guidelines are based upon very large observational cohorts (>1000 patients) and studies of >8 year follow up, not "One small retrospective study looked at 4 month follow up on 100 patients in ED where CACS score was taken, along with other tests and concluded that a score of 0 could permit a discharge." There are numerous studies documenting efficacy, without the need of a functional test.	EbGS is aware of the literature used by the NICE guidelines, and that their rationale for coverage of CACS is based on a favorable cost-effectiveness evaluation that is specific to the UK healthcare delivery system. The quote identified is directly from the WA HTA clinical committee findings, not from the EbGS. While the WA HTA clinical committee elected to comment on this one study in their findings report, EbGS agrees that there are other larger case series presented and discussed in the WA HTA report. A total of 5 case series that evaluated patients presenting to the ED were identified. Given that none used a control group, the ability to draw conclusions about the impact of CACS on clinical decisions is limited.
	3	Large studies have documented efficacy of CAC in the emergency department and the ability to safely discharge patients. In a study of 1031 patients that presented to the emergency room with chest pain and had a non-ischemic electrocardiogram, normal initial troponin, and no history of CAD, Nabi et al showed that a CAC score of 0 predicted a normal nuclear stress test and excellent short term outcome.[1] Event rate was 0.3% at 6 months for those persons who had a CAC of zero (>61% of the total cohort).	[1]Nabi is a case series (N=1031) of patients with chest pain suggestive of ischemia without elevated troponin or EKG changes admitted for observation. Outcomes were as described by the commenter. As a case series, it is unclear how this compares with evaluation using other modalities.
	4	Furthermore, there have been studies with up to 8 years outcome after a negative CAC scan in the ED setting (without any functional testing), validating the safety of a CAC test, demonstrating no events in those with zero calcification.[2]	[2]Georgiou 2001 was published before the date of the WA HTA report and the NICE guideline. The EbGS bases their guidance documents on reviews of the literature that utilize the highest standards of evidence-based medicine. Studies are included or excluded based on transparent, reproducible

Stakeholder	#	Comment	Disposition
			criteria; therefore the EbGS does not investigate individual studies. The EbGS assumes that the conclusions reached by the authors of these reviews weigh all the available evidence in accordance with the principles of evidence based medicine, and does not attempt to re-review the entire body of evidence to reach its own conclusions.
	5	A meta-analysis of 64,873 patients followed over 4.2 years similarly showed a 0.13% annual event rate for patients with 0 CAC scores.[3] This results in a negative predictive power of >99.5% for a score of zero (no detectable CAC) in symptomatic persons, which is higher than other advocated strategies such as stress testing or nuclear imaging in this setting. There are at least 6 prospective studies documenting the efficacy of the use of CAC testing in the ED or acute setting, all documenting the safety and efficacy of using coronary artery calcium in this setting.	[3]Sarwar 2009 was a systematic review that included a meta-analysis of 7 studies of symptomatic patients (N=3924). Inclusion criteria were broad and without limitations in study design. While not specifically stated, it appears that none of the seven had a control group, making this meta-analysis simply a large case series. It is unclear how CACS compares to evaluation of the symptomatic patient using other modalities. Of those with zero calcium, there was a 1.8% event rate over a mean follow up of 3.5 years. There was a much larger population of asymptomatic participants (71,595). (Unclear what the 64,873 number cited by the commenter refers to.) Citations for the 6 prospective studies not provided.
	6	We would encourage you to consider this indication, given the support of the American Heart Association[4],	AHA guidelines state the following: "Coronary calcium assessment may be reasonable for the assessment of symptomatic patients, especially in the setting of equivocal treadmill or functional testing (Class IIb, Level of Evidence: B). There are other situations when CAC assessment might be reasonable. CACP measurement may be considered in the symptomatic patient to determine the cause of cardiomyopathy (Class IIb, Level of Evidence: B). Also, patients with chest pain with equivocal or normal ECGs and negative cardiac enzyme studies may be considered for CAC assessment (Class IIb, Level of Evidence: B)." The AHA uses the following classification for their recommendations: • Class I: Conditions for which there is evidence, general agreement, or both that a given procedure or treatment is useful and effective. • Class II: Conditions for which there is conflicting evidence, a divergence of opinion, or both about the usefulness/efficacy of a procedure or treatment. • Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Stakeholder	#	Comment	Disposition
			• Class IIb: Usefulness/efficacy is less well established by evidence/opinion. • Class III: Conditions for which there is evidence, general agreement, or both that the procedure/treatment is not useful/effective and in some cases may be harmful. The AHA uses the following classification for their Level of Evidence • Level of Evidence A: Data derived from multiple randomized clinical trials • Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies • Level of Evidence C: Consensus opinion of experts EbGS makes their decisions based on the best available evidence of effectiveness and harms as represented in the source evidence documents, not on the basis of guidelines that are of unknown quality. In addition, the recommendation on the use of CACS is rated class IIb, for which "efficacy is less well established".
	7	American College of Cardiology[5],	The ACC consensus statement states the following for symptomatic patients: "In direct-comparison studies, CAC detection in the symptomatic person has been shown to be comparable to nuclear exercise testing in the detection of obstructive CAD. Given the prognostic information that is implicit in exercise capacity, even when it is combined with imaging, fast CT starts with a disadvantage compared with existing modalities in symptomatic patients who can exercise. Anatomic testing, such as cardiac CT (whether with contrast in the form of CT angiography or without contrast, such as CAC assessment), should be relegated to second line testing or considered when functional testing is either not possible or indeterminate." "Considerable discussion among the group focused on the best and most proper way to assess clinical appropriateness of tests such as CAC measurement *since there have been no clinical trials to evaluate the impact of CAC testing on clinical outcomes* [italics added] in either symptomatic or asymptomatic patients."

Stakeholder	#	Comment	Disposition
			Also: "Is there evidence that coronary calcium measurement is better than other potentially competing tests in intermediate risk patients for modifying cardiovascular disease risk estimate? In general, CAC measurement has not been compared to alternative approaches to risk assessment in head-to-head studies. This question cannot be adequately answered from available data." And: "Is there a role of CAC testing in patients with atypical cardiac symptoms? Evidence indicates that patients considered to be at low risk of coronary disease by virtue of atypical cardiac symptoms may benefit from CAC testing to help in ruling out the presence of obstructive coronary disease. Other competing approaches are available, and most of these competing modalities have not been compared head-to-head with CAC." EbGS makes their decisions based on the best available evidence of effectiveness and harms as represented in the source evidence documents, not on the basis of guidelines that are of unknown quality.
	8	UK NICE Guidelines and European guidelines[6] in this regard.	The NICE guidelines are included in the guidance document; EbGS is aware of their recommendations and that their rationale for coverage of CACS is based on a favorable cost-effectiveness evaluation that is specific to the UK healthcare delivery system. The European guidelines use essentially the same classification system for their recommendations and evidence levels as the AHA. In addition they include suggested wording based on the Class as follows: • Class I – Is recommended • Class IIa – Should be considered • Class IIb – May be considered • Class III – Is not recommended

Stakeholder	#	Comment	Disposition
			Their recommendations are as follows: "Computed tomography for coronary calcium should be considered for cardiovascular risk assessment in asymptomatic adults at moderate risk." Class IIa Recommendation, Level of Evidence: B, GRADE: Weak EbGS makes their decisions based on the best available evidence of effectiveness and harms as represented in the source evidence documents, not on the basis of guidelines that are of unknown quality.
	9	"The committee noted that national guidelines do not endorse the use of CACS, though some have permissive statements for use of the test." There are actually several national guidelines that endorse the use of CACS, that perhaps were not made available to the committee.	As above, this is a direct quote from the findings of the WA HTA Clinical Committee. The WA HTA report that served as their evidence source (and was also one of the source documents for this guidance) included guidelines from the following entities: ACCF/AHA 2007 Clinical Expert Consensus document on CACS by CT in global CV risk assessment and in evaluation of patients with chest pain. (see comment #7). AHA Committee on CV Imaging and Intervention: Assessment of coronary artery disease ay CCT 2006 (see comment #6). ACC/AHA expert consensus document on EBCT for the diagnosis and prognosis of CAD (2000). American College of Radiology Appropriateness Criteria (2008): CACS received a score of 3 (most appropriate = 9, least appropriate = 1)
	10	The most notable and specific guideline covering this indication is the 2010 ACCF/AHA Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines.[7] This statement advocates for the use of coronary calcium testing for intermediate risk asymptomatic persons, as well as for those with diabetes. This was reinforced by another guideline in 2012 from the European Guidelines on cardiovascular disease prevention in clinical practice (version	The ACCF/AHA guideline (2010) referenced by the commenter makes the following recommendations regarding asymptomatic patients: CLASS IIa (is reasonable to perform) 1. Measurement of CAC is reasonable for cardiovascular risk assessment in asymptomatic adults at intermediate risk (10% to 20% 10-year risk). (*Level of Evidence: B*) CLASS IIb (may be considered) 1. Measurement of CAC may be reasonable for cardiovascular risk

Stakeholder	#	Comment	Disposition
		2012).[6]	assessment in persons at low to intermediate risk (6% to 10% 10-year risk). (*Level of Evidence: B*) CLASS III: NO BENEFIT (should not be done) 1. Persons at low risk (<6% 10-year risk) should not undergo CAC measurement for cardiovascular risk assessment. (*Level of Evidence: B*) CLASS IIa (is reasonable to perform) 1. In asymptomatic adults with diabetes, 40 years of age and older, measurement of CAC is reasonable for cardiovascular risk assessment. (*Level of Evidence: B*) For European guidelines, see comment #8. Class IIb recommendations are used when "efficacy is less well established". EbGS makes their decisions based on the best available evidence of effectiveness and harms as represented in the source evidence documents, not on the basis of guidelines that are of unknown quality.
	11	In 2010, the ACCF, AHA, and other organizations, including the Society for Cardiovascular Computed Tomography and the American College of Radiology published appropriate use criteria for cardiac CT for selected patient indications.[8] They rated calcium scoring as appropriate in patients at low or intermediate risk but uncertain (optional) in high risk patients.	The referenced guideline states, in summary, patients: "Use of noncontrast computed tomography (CT) for calcium scoring was rated as appropriate within intermediate- and selected low-risk patients." For asymptomatic patients, appropriateness ranged from appropriate to inappropriate depending on global CHD risk estimate. They consider it appropriate for patients at low risk (<10%) with a positive family history of premature CHD, or for patients with intermediate risk (10-20%). Appropriateness was uncertain for high risk asymptomatic patients, and inappropriate for low risk asymptomatic patients (<10%). For symptomatic patients, no appropriateness scores were provided for CACS (only for CCTA). EbGS makes their decisions based on the best available evidence of effectiveness and harms as represented in the source evidence documents, not on the basis of guidelines that are of unknown quality.
	12	The 2007 ACC Expert Consensus document on Coronary Artery Calcium also endorsed the use of CAC testing for asymptomatic persons, stating "CAC scoring has an increasingly high level of quality evidence on its role in	With regard to asymptomatic patients at intermediate risk, the guideline states the following: "The Committee judged that it may be reasonable to consider use of CAC

Stakeholder	#	Comment	Disposition
		risk stratification of asymptomatic patients. Recent evidence is supportive that measurement of CAC is predictive of CHD death or MI at 3 to 5 years… The accumulating evidence suggests that asymptomatic individuals with an intermediate FRS may be reasonable candidates for CHD testing using CAC as a means of modifying risk prediction and altering therapy."[5]	measurement in such patients based on available evidence that demonstrates incremental risk prediction information in this selected (intermediate risk) patient group. This conclusion is based on the possibility that such patients might be reclassified to a higher risk status based on high CAC score, and subsequent patient management may be modified." Despite the statement cited by the commenter and the theoretical possibility, there remains no firm evidence to support use of CACS "as a means of modifying risk prediction and altering therapy." EbGS makes their decisions based on the best available evidence of effectiveness and harms as represented in the source evidence documents, not on the basis of guidelines that are of unknown quality.
	13	Furthermore, the 2010 ACC/AHA Guidelines and the 2012 European guidelines both advocate for the test, with Class IIA recommendations for CAC in asymptomatic persons. This is a stronger recommendation than most other tests evaluated, including advanced lipid testing, C-reactive protein testing, homocysteine testing and treadmill testing, all covered services in your system. It is not consistent to reimburse tests with lower recommendations by the ACC/AHA Guidelines without covering CAC in the same setting. There is no standard to show that a diagnostic test should improve outcomes, it is up to the treatment modality to cover the test.	See comments #8 and #10. While the EbGS appreciates the recommendations from the ACC/AHA, they make their decisions based on the best available evidence of effectiveness and harms as represented in in the source evidence documents, not on the basis of guidelines that are of unknown quality. In addition, the cost of CACS is substantially higher than the tests mentioned by the commenter, and potentially higher risk given the radiation exposure incurred by the patient. Further, a number of these tests will be evaluated in a subsequent coverage guidance.
	14	Several randomized prospective trials have demonstrating that undergoing CAC testing has resulted in lower event rates or lower Framingham Risk (Eisner study and St Francis Randomized Trial). This documents that those undergoing CAC testing have evidence of improved health status. This is more substantial and validated data than is available for algorithms that involve Framingham risk assessment, lipid testing or other commonly covered tests. Thus again, this test has or exceeds the necessary evidence for coverage, and exceeds that of many other covered tests used in similar context.	Citations not provided, unable to confirm findings.
	15	All current guidelines, from the European Society of Cardiology,[1] American College of Cardiology and American Heart Association[2], all give coronary artery calcium a Class IIa recommendation for use in asymptomatic modest (intermediate) risk patients. Regarding CAC, the Joint ESC Statement[1]	EbGS disagrees that "all current guidelines" recommend use of CACS in asymptomatic intermediate risk patients, since the USPSTF does NOT recommend use of CACS in asymptomatic patients, regardless of risk.

Stakeholder	#	Comment	Disposition
		concludes "Although calcium scanning is widely applied today, it is especially suited for patients at moderate risk. The radiation exposure with the properly selected techniques is <1 mSv." (Class IIa Recommendation).	
	16	The European Working Group made separate guidelines in 2011[9] also recommending this test in asymptomatic persons at intermediate risk, and made the very succinct statement "In summary, there is overwhelming evidence that coronary calcification represents a strong marker of risk for future cardiovascular events in asymptomatic individuals and has prognostic power above and beyond traditional risk factors." We agree that demonstrating improved mortality in those undergoing a CAC scan would be optimal, but not practical. The sample size for such a study has been estimated around 100,000 persons. We have no outcome data showing improved mortality or morbidity with **ANY** cardiac test currently available. There is **NO** data that exercise treadmill testing, echocardiography, stress imaging or even cardiac catheterization improve outcomes; yet we understand as clinicians the important role they each play. Even total risk assessment (such as calculating Framingham Risk) has not been validated to improve outcomes.[3] Thus, the cumulative evidence is very strong supporting CAC testing in the specific population of intermediate risk, and consistent with every published guideline, should be covered and applied in this population. Thank you for your time and consideration.	EbGS agrees that there is no evidence of improved outcomes with the use of CACS, and it has the potential to be more costly and less safe than alternative diagnostic modalities. With regard to asymptomatic patients, EbGS disagrees that "every published guideline" supports coverage, since the USPSTF does NOT recommend use of CACS in asymptomatic patients.

CG - Coronary computed tomography angiography

Question: How should the Coverage Guidance *Coronary computed tomography angiography* be applied to the Prioritized List?

Question source: Evidence-based Guideline Subcommittee

Issue: At the February 7, 2013 EbGS meeting, the subcommittee finalized the draft Coverage Guidance that states “Coronary computed tomography angiography is recommended for noncoverage”.

While there is evidence to support its use and some intriguing cost-effectiveness models, the subcommittee decided that CCTAs adoption into Emergency Department use was as yet unclear, because one standard triage model, with accepted estimates of low-intermediate risk, is not widely accepted. There was a concern for overutilization without appropriate pre-risk assessment, as well as a large variation in the follow up strategies. Additionally, the intervention is not without harm in terms of increased radiation. The subcommittee meembers felt that more experience and acceptable standard triage models needed to be developed before adoption of this technology as part of a benefits package.

Current Prioritized List Status

Code	Code Description	Current Placement
75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluatio	DMAP Excluded File

Recommendations:

1) Make no change to the Prioritized List. CCTA is currently noncovered by Exclusion.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: CORONARY COMPUTED TOMOGRAPHY ANGIOGRAPHY

DRAFT AS REFERRED BY EBGS TO VBBS ON 2/7/2013

HERC COVERAGE GUIDANCE

Coronary Computed Tomography Angiography (CCTA) is not recommended for coverage.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCES

Clark, E.E. (2011). *Coronary computed tomographic angiography*. Portland: Center for Evidence-based Policy. Retrieved August 31, 2012, from http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/index.cfm

Institute for Clinical and Economic Review. (2012). *Update on Coronary CT Angiography: New clinical trial evidence*. Boston: Institute for Clinical and Economic Review. Retrieved September 18, 2012, from http://www.icer-review.org/index.php/Completed-Appraisals/ccta.html

National Institute for Health and Clinical Excellence (NICE). (2010*). Chest pain of recent onset: Assessment and diagnosis of recent onset chest pain or discomfort of suspected*

cardiac origin. London: NICE. Retrieved August 31, 2012, from http://publications.nice.org.uk/chest-pain-of-recent-onset-cg95

Ollendorf, D.A. (2009). *Coronary computed tomographic angiography for the detection of coronary artery disease*. Boston: Institute for Clinical and Economic Review. Retrieved September 18, 2012, from http://www.icer-review.org/index.php/Completed-Appraisals/ccta.html

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Coronary computed tomographic angiography (CCTA) is a diagnostic imaging test that uses a computed tomographic (CT) scanner to non-invasively image the coronary arteries of the heart. Since obstructive coronary artery disease (CAD) is common in the United States (US) adult population and is responsible for most of the heart attacks, the ability to identify stenosis of the coronary arteries in patients with chest pain becomes important. Coronary computed tomographic angiography can be used in place of other intermediate tests such as stress electrocardiogram (ECG), stress nuclear perfusion imaging and stress echocardiography (ECHO) to either increase or decrease the likelihood of CAD as the cause of chest pain. In contrast to CCTA which provides anatomic information about the coronary arteries, these tests evaluate myocardial ischemia (indicators that the heart muscle is not receiving adequate blood flow).

The development of multi-slice CT scanners has led to increased use of CCTA with nearly half of all cardiology practices in the US leasing or owning cardiac CT equipment. Advocates of CCTA recommend it for patients with low to intermediate risk of CAD who present with acute onset of chest pain [primarily in the emergency department (ED) setting] and with stable chest pain suggestive of CAD (primarily in the outpatient setting). Additionally CCTA is being advocated for patients with high risk of CAD and atypical chest pain, evaluation of patients with symptoms after coronary stent placement and screening of asymptomatic patients with high risk of CAD. Both patient selection criteria and equipment capabilities affect the diagnostic efficacy of CCTA. Radiation dose and financial costs for CCTA are significant.

Evidence Review

MED Report (Clark 2011)

Patient and technical factors affect the use and quality of CCTA. Patients selected for CCTA: 1) should not be obese; 2) should not have arrhythmias or heart rates more than 65 beats per minute; 3) should be able to hold their breath for more than 20 seconds; 4) should be able to tolerate a standard dose of contrast material; and 5) should not have significant coronary artery calcifications. Multi-slice CT scanners should have at least 64 slices to perform CCTA adequately. The performance and interpretation of CCTA requires special training, and a minimum of 50 cases per year is recommended to maintain competence in the procedure.

Coronary computed tomographic angiography has a very high sensitivity (≥ 97%) and moderate to moderately high specificity (72-93%) for the detection of coronary artery stenosis, based on moderate quality evidence. A CCTA test sensitivity of 97% means it will detect almost all (97%) of those who have at least one obstructed coronary artery, and only miss 3% of such patients. Thus if the CCTA test is negative it will very likely be a "true negative" and the patients can be sent home. On the other hand, a CCTA test specificity of 72% to 93% means that in a population of patients without obstructive CAD, the test will only be negative 72% to 93% of the time. In the other 7% to 28% of patients without obstructive CAD, it will be a falsely positive test. Practically speaking, a positive CCTA test will often require further testing (invasive angiography) in order to determine if it is a true positive test or a false positive test. These results can be further influenced by the prevalence of obstructive CAD in the population on which the test is used, as described in the body of the report.

These performance characteristics support the use of CCTA to “rule out” obstructive CAD in ED patients with acute chest pain and normal ECGs and initial cardiac enzymes, and in outpatients with stable chest pain, a population with low to intermediate probability of obstructive CAD. Coronary computed tomographic angiography in these situations can be used to identify those patients with no CAD (i.e., negative CCTA in a patient with low to intermediate [pre-test] probability of CAD), so they can be safely discharged from the ED without further evaluation. This is substantiated by one small RCT (n = 197) and seven observational studies suggesting that ED patients with low to intermediate pre-test probability of CAD and a negative CCTA do not have increased cardiac events over the subsequent year.

In patients with low to intermediate risk of CAD, CCTA appears to have better diagnostic accuracy than stress ECG and stress nuclear perfusion imaging, based on low to moderate quality evidence. A single, poor quality, before and after study suggests that CCTA may reduce the number of subsequent tests including stress nuclear

perfusion imaging and invasive coronary angiography. A number of validated clinical prediction rules exist that clinicians can use to assess the [pre-test] probability of obstructive CAD prior to ordering a CCTA.

The MED report did not find studies that addressed screening asymptomatic patients, although they did not specifically search for such evidence.

The amount of radiation dose for CCTA is similar to a CT scan of the abdomen or an invasive coronary angiography, and is estimated to be 8-14 mSv. In addition to radiation exposure and contract reactions or nephropathy, the other potential harms of CCTA are incidental findings. There are relative benefits and harms from the incidental findings noted on CT of the chest (findings in the chest obtained during a CCTA). Approximately 40% to 80% of patients undergoing CCTA will have a finding that is not related to the coronary arteries; 5% to 20% will have a finding deemed clinically important enough for further evaluation. Although some of the patients with these incidental findings will have been judged to have received some benefit, findings from the few studies that have examined this question suggest that the proportion of patients receiving some benefit is very low, while additional risks, anxieties and costs are generated by the additional investigations.

[Evidence Source]

NICE Guideline: Chest Pain of Recent Onset

Acute chest pain (evaluation in the ED)
The NICE guideline does not recommend the use of CCTA as a first line test for evaluation of patients in the ED with acute chest pain. The guideline assessment of CCTA in this setting is as follows:

In the past few years a number of pilot studies have examined the utility of multislice CT in the ED in the differential diagnosis of acute chest pain. To date these studies consist of small numbers of patients (around 100 patients), they have been conducted primarily in the USA, and they are limited in scope because each represents the experience of one centre. There are differences in study protocols, patient recruitment, scanners used, angiography protocols and angiographic analyses. This makes direct comparison of these studies difficult with respect to reviewing and interpretation. The authors of these studies, while stating the potential promise of multislice CT, do emphasise that further evaluation needs to be done. There are other considerations as given below:

- Currently the use of multislice CCTA in the ED would reduce diagnostic time, however this becomes less important with the evolving technology of reduce waiting time for biomarker assay results.

- Multislice CCTA will identify a group of patients with sub clinical CAD i.e. disease that is not the cause of the current chest pain episode. The significance of this will need to be evaluated in large studies in the recruitment of unselected consecutive chest pain patients.
- It has not been established if the patient in the ED should receive a dedicated CT coronary angiogram, or have an entire thoracic scan. A dedicated CT coronary angiogram would give the best possible images of the coronary arteries, but allows limited visualisations of other structures that may be responsible for chest pain. The benefit of an entire scan is that it would rule out pulmonary embolism and aortic dissection, however, this would involve increased radiation dose, increased scanning time, and possible less than optimal visualisation of coronary arteries.
- The best use of the multislice CT scanner in the ED has not been established. Images could be obtained as soon as possible after initial assessment (history, risk factors, examination) and the first set of cardiac enzymes. In which case the multislice CCTA results would be used as a component of the decision to discharge or admit the patient. Alternatively multislice CCTA could be used to aid in determining what further monitoring and treatment is indicated after a decision has been made to admit the patient. Hence it is unclear at which point multislice CCTA would fit into an algorithm used in the ED, and what would be the most cost-effective use of multislice CCTA in the ED. This may have implications on cost-effectiveness.
- Current preliminary findings indicate that multislice CCTA in the ED has potential for the ruling out of CAD. When stenosis of > 50% is detected the patient would undergo further non invasive or invasive testing, but the precise course of further evaluation is uncertain at this stage due to the limited literature. Resolving this could potentially be a large piece of work, and would impact on the current care pathway.
- Owing to the limited number of studies, health economic evaluation of multislice CCTA in the ED may be difficult, particularly as there is no information regarding the subsequent testing of patients when stenosis is > 50%.

Stable Chest Pain (outpatient evaluation)

The NICE guideline makes the following recommendations pertaining to CCTA:

> In people without confirmed CAD, in whom stable angina cannot be diagnosed or excluded based on clinical assessment alone, estimate the likelihood of CAD (see Table 1). Take the clinical assessment and the resting 12-lead ECG into account when making the estimate. Arrange further diagnostic testing as follows:
>
> - If the estimated likelihood of CAD is 61–90%, offer invasive coronary angiography as the first-line diagnostic investigation if appropriate.
> - If the estimated likelihood of CAD is 30–60%, offer functional imaging as the first-line diagnostic investigation.
> - If the estimated likelihood of CAD is 10–29%, offer coronary artery calcium scoring as the first-line diagnostic investigation. If the calcium score is:
>   - zero, consider other causes of chest pain
>   - 1–400, offer 64-slice (or above) CCTA
>   - greater than 400, offer invasive coronary angiography.

Table 1. Percentage of people estimated to have coronary artery disease according to typicality of symptoms, age, sex and risk factors

	Non-anginal chest pain				Atypical angina				Typical angina			
	Men		Women		Men		Women		Men		Women	
Age (years)	**Lo**	**Hi**	**Lo**	**Hi**	**Lo**	**Hi**	**Lo**	**Hi**	**Lo**	**Hi**	**Lo**	**Hi**
35	3	35	1	19	8	59	2	39	30	88	10	78
45	9	47	2	22	21	70	5	43	51	92	20	79
55	23	59	4	25	45	79	10	47	80	95	38	82
65	49	69	9	29	71	86	20	51	93	97	56	84

For men older than 70 with atypical or typical symptoms, assume an estimate > 90%.
For women older than 70, assume an estimate of 61–90% EXCEPT women at high risk AND with typical symptoms where a risk of > 90% should be assumed.

Values are percent of people at each mid-decade age with significant coronary artery disease (CAD)[1].
Hi = High risk = diabetes, smoking and hyperlipidaemia (total cholesterol > 6.47 mmol/litre).
Lo = Low risk = none of these three.
The shaded area represents people with symptoms of non-anginal chest pain, who would not be investigated for stable angina routinely.
Note: These results are likely to overestimate CAD in primary care populations. If there are resting ECG ST-T changes or Q waves, the likelihood of CAD is higher in each cell of the table.

[1] Adapted from Pryor DB, Shaw L, McCants CB et al. (1993) Value of the history and physical in identifying patients at increased risk for coronary artery disease. *Annals of Internal Medicine 118*(2),81-90.

Discussion of the evidence for CCTA in the NICE guideline is summarized as follows:

Advantages and Disadvantages

The advantages of CCTA compared with coronary angiography are that it is less invasive, it can capture thousands of images of a beating heart in seconds, and it may also be relatively less expensive. However 64-slice CCTA requires an injection of iodine-containing contrast and has been regarded as a moderate to high radiation diagnostic technique (12 to 15 mSv), although recent technical advances are improving radiation efficiency considerably. Further disadvantages of 64-slice CT coronary angiography include; poor correlation with coronary angiography in calcified vessels as extensive calcification obscures imaging of coronary arteries, poor correlation with coronary angiography for quantifying stenosis severity when > 50% and in vessels < 2 mm, no functional assessment of myocardial ischaemia and the potential for motion artifacts due to beating of the heart.

Evidence for Diagnostic Efficacy

For the diagnosis of CAD, five systematic reviews of 64-slice CCTA reported higher sensitivities (ranging from 96% to 99%) and specificities (ranging from 88% to 97%) compared with the non-invasive tests of stress ECHO, stress myocardial perfusion scintigraphy using single photon emission computed tomography (SPECT), stress MR perfusion imaging and stress MR wall motion abnormalities. There is evidence from short term diagnostic economic models that for patients with a low to moderate pre-test likelihood of CAD, 64-slice CCTA (with or without prior exercise ECG) as the initial investigation is cost-effective compared to invasive coronary angiography alone.

Evidence for Risks

The NICE guideline reports on a study that estimated the life attributable risk (LAR) of cancer incidence associated with radiation exposure from 64-slice CCTA. These LARs varied fivefold depending on age and gender, from 1 in 143 for a 20 year old woman to 1 in 3261 for an 80 year old man. The effective dose of radiation from a single scan was reported as a range from 9 to 29 mSv.

Economic Evaluations

Of the six economic evaluations included in evidence reviewed for this guideline, two addressed CCTA. Neither one specified whether they applied to stable or acute chest pain. One compared exercise ECG, dobutamine stress ECHO, dobutamine stress MRI, electron beam CT with calcium scoring and multislice CT coronary angiography as initial diagnostic tests, where only those patients with a positive or indeterminate test result would subsequently undergo invasive coronary angiography (Dewey 2007). Based on this analysis, multislice CT coronary angiography clearly dominates exercise ECG, stress ECHO, stress MRI and calcium scoring with electron beam CT as initial diagnostic strategies for CAD at all levels of disease prevalence modelled. This model

did not include any costs for harms of radiation exposure or for evaluation of incidental findings.

The other economic analysis compared 64-slice CCTA compared with exercise ECG, myocardial perfusion scintigraphy with SPECT and invasive coronary angiography in the investigation of CAD (Mowatt 2008). The analysis found that 64-slice CCTA appears to be superior to myocardial perfusion scintigraphy with SPECT for the diagnosis of CAD in all clinical dimensions and also in terms of cost. The report concludes that the high sensitivity and negative predictive value of 64-slice CCTA suggest scope for avoiding unnecessary invasive coronary angiography in those referred for investigation but who do not have CAD. Given the small risk of death associated with invasive coronary angiography, 64-slice CCTA might also confer a small immediate survival advantage. Avoidance of unnecessary invasive coronary angiography may result in cost savings, even if positive results require confirmation by invasive coronary angiography. However, at higher CAD prevalence, these cost savings are likely to disappear. This model included the costs of complications arising from the interventions, but did not specifically address the harms of radiation or the additional costs of evaluation of incidental findings.

The NICE guideline development group performed their own economic analysis of a diagnostic strategy that incorporated the use of calcium scoring using 64-slice CCTA as a precursor to full 64-slice CCTA. This was done as a way of minimizing the risk of radiation from 64-slice CCTA, a risk which was not explicitly incorporated into the other models. Results of the base case analysis indicate that for lower risk groups (5% and 20%), the use of calcium scoring as a first line testing strategy is likely to be cost-effective and should be followed by either 64-slice CCTA alone or with additional invasive coronary angiography as a confirmatory 3rd test. In higher risk populations, (CAD prevalence greater than 40%), a strategy of sending all patients directly to invasive coronary angiography is likely to be cost-effective. The model indicates that myocardial perfusion scintigraphy with SPECT is excluded through dominance or extended dominance at every level of CAD prevalence. It also indicates that exercise ECG is only cost-effective as a first line investigation strategy at 5% CAD prevalence, but that even in this instance replacing exercise ECG with calcium scoring is likely to improve effectiveness at a reasonable level of additional cost.

[Evidence Source]

Institute for Clinical and Economic Review Report

This cost effectiveness analysis evaluated a variety of diagnostic strategies using stress ECHO, CCTA, SPECT and invasive coronary angiography in two scenarios, in the outpatient setting and in the ED assuming either a 30% or 10% prevalence of CAD. All

analyses were performed without considering harm, benefit, or costs of radiation-exposure or incidental findings, although they did incorporate an estimate for the evaluation of pulmonary nodules. *"CCTA alone"* resulted in about 14% incidental findings and thus required follow-up as compared to 0% to 5% in the other strategies. Strategies including either CCTA or SPECT as the first or only test exposed all patients to radiation, as opposed to 20% to 40% of patients exposed in strategies with stress-ECHO as the first or only test.

Asymptomatic patients

Use of CCTA as a screening tool in asymptomatic patients was not evaluated in this report.

Emergency department patients with chest pain

When used as triage in the ED, they found that the model "is consistent with other published cost-effectiveness analyses in suggesting that when used as part of a triage strategy for low-to-intermediate risk chest pain patients in the ED, CCTA will allow the more rapid discharge of nearly half of all patients and decrease the number of false negative diagnoses while reducing the number of angiographies compared to the current standard of care. According to the model CCTA is also cost-saving, with about $719 in savings per patient in comparison to SOC [standard of care]. Taking into account the additional follow-up costs for the 14% of patients who undergo CCTA and have incidental findings (approximately $100 per patient receiving CCTA), the cost-savings are reduced to approximately $619, but remain in favor of CCTA. However, CCTA does expose every patient to radiation, whereas only about 43% of the patients in SOC are exposed via invasive angiography."

In 2012, ICER updated this report to incorporate the findings of two large, multicenter randomized clinical trials of CCTA versus standard ED evaluation. "These trials enrolled nearly 2500 patients at 14 sites, and unlike the earlier trial, included patients at intermediate risk of acute coronary syndromes. Findings were very similar between the two studies. CCTA was found to significantly increase the percentage of patients discharged home from the ED relative to standard care, and reduced time in hospital by seven to eight hours on average. There were no deaths at 28 to 30 days in either study, and no statistically-significant differences in rates of major cardiovascular events. In one study, however, patients in the CCTA arm received more downstream diagnostic testing than those receiving standard evaluation; the increased costs from additional testing eliminated any savings from earlier discharge in the CCTA arm, and average total strategy costs were found to be similar between the groups."

"ICER previously found the evidence on comparative clinical effectiveness to be 'Comparable' between CCTA and standard triage care in the ED setting; these recent findings confirm the original rating. The original rating for comparative value was 'High',

however, based primarily on evidence of earlier ED discharge. In light of these recent data on increased resource use following CCTA, we [ICER] would recommend changing CCTA's comparative value rating to 'Reasonable/Comparable'."

Outpatients with chest pain

In the outpatient model, "at a CAD prevalence of 30%, CCTA produces a higher number of true positives and fewer false negatives relative to other 1- or 2-test strategies, and lower diagnostic phase costs than nearly all other tests; at a prevalence of 10%, differences in test performance are diminished but the pattern of costs remains the same. When alternative estimates of CCTA's diagnostic accuracy are employed, the balance of false-positive and false-negative shifts, but has little impact on comparative cost between the strategies. However, when a more aggressive strategy for management of mild-moderate stenosis is employed, CCTA becomes more costly than several other strategies due to a higher rate of referral for invasive coronary angiography."

"Considering a lifetime horizon, quality-adjusted life expectancy is quite similar across the strategies, with a difference of only about 2 weeks between the most and least effective strategies. At 30% CAD prevalence, a single-test strategy with CCTA appears to be more effective and less costly than SPECT, and a reasonable value when compared to Stress ECHO (incremental cost-effectiveness ratios of $13,000 to $16,000/QALY). When prevalence is reduced to 10%, however, while cost-effectiveness is similar for CCTA vs. stress ECHO, SPECT is more effective than CCTA at a ratio of approximately $80,000/QALY. A shift from conservative to aggressive management of mild-moderate stenosis affects the lifetime results only marginally, as does the use of alternative estimates of CCTA's diagnostic accuracy."

"Because the range of effectiveness results is so narrow, the model is highly sensitive to changes in selected parameters, in particular the costs of the various strategies. For example, at a cost of $248 or less, CCTA would dominate all other strategies, while for CCTA costs of $1,083, $1,916, and $2,749, the cost-effectiveness ratios would be $50,000/QALY, $100,000/QALY, and $150,000/QALY, respectively."

[Evidence Source]

Overall Summary

Coronary computed tomographic angiography may be useful to "rule out" obstructive CAD in ED patients with acute chest pain and normal ECGs and initial cardiac enzymes, and in outpatients with stable chest pain in a population with low to intermediate probability of obstructive CAD. Cost-effectiveness analyses show either that CCTA is comparable or less costly than other diagnostic strategies, although for the most part, they did not consider the economic consequences of the harms of radiation

or further evaluation of incidental findings. However, understanding how CCTA would be used in a clinical practice setting, and whether the cost-effectiveness assumptions are applicable as it would be used in clinical practice, is unclear. Use in other patient populations is not recommended due to unacceptable false positive or false negative results. Use in asymptomatic patients has not been evaluated.

PROCEDURE

Coronary computed tomographic angiography

DIAGNOSES

Coronary artery disease
Chest pain

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
410	Acute myocardial infarction
411	Other acute and subacute forms of ischemic heart disease
413	Angina pectoris
414	Other forms of chronic ischemic heart disease
ICD-9 Volume 3 (Procedure Codes)	
87.41	Computed axial tomography of the heart
CPT Codes	
75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts, with contrast, including 3D image post-processing
HCPCS Level II Codes	
None	

Note: Inclusion on this list does not guarantee coverage

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

HERC Coverage Guidance – Coronary Computed Tomography Angiography
Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
ICER	1	We read with great interest your draft guidance on this topic, and we appreciate very much being one of the trusted sources you cite in the guidance. We realize that you often include verbatim text from other reviews in your guidance, but we wanted to call your attention to text from our review that might be misconstrued as coming from the HERC rather than our organization. Specifically, text on page 9 of your guidance reads "the original rating for comparative value was 'High', however, based primarily on evidence of earlier emergency department discharge. In light of these recent data on increased resource use following CCTA, we would recommend changing CCTA's comparative value rating to 'Reasonable/Comparable'." Some stakeholders might feel as though you are making a recommendation to change ICER's rating of comparative value, when in fact it was ICER itself that made the recommendation. You might consider clarifying this by putting a parenthetical next to word "we" indicating the source of the recommendation.	Thank you for your comment. The EbGS appreciates the importance of clarifying the source of recommendations. Change made to the document as suggested.

CG - Continuous blood glucose monitoring in diabetes mellitus

Question: How should the Coverage Guidance *Continuous blood glucose monitoring in diabetes mellitus* be applied to the Prioritized List?

Question source: Health Technology Assessment Subcommittee

Current Prioritized List Status:

Code	Code Description	Current List Placement
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording	10 TYPE I DIABETES MELLITUS
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report	10 TYPE I DIABETES MELLITUS
S1030	Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use cpt code)	DMAP Ancillary Codes File
S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use cpt code)	DMAP Ancillary Codes File

Coverage Guidance:

Real-time continuous glucose monitoring systems should be covered for Type 1 diabetes mellitus patients with HbA1c levels greater than 8.0% or a history of recurrent hypoglycemia, for whom insulin pump management is being considered, initiated, or utilized.

Real-time continuous glucose monitoring systems should not be covered for Type 2 diabetes mellitus patients.

Retrospective continuous glucose monitoring systems should be covered for Type 1 diabetes mellitus and should not be covered for Type 2 diabetes mellitus.

HERC Staff Assessment and issues for discussion

Initially the coverage guidance had read "Retrospective CGM systems should not be covered for either Type 1 or Type 2 DM." Public comment and live testimony convinced the subcommittee to recommend coverage in select groups of Type 1 diabetics for continuous glucose monitoring. Retrospective monitoring was felt to be inexpensive ($100) and may offer additional input in certain clinical situations, despite the lack of current evidence, and so was also recommended

for coverage. The VBBS/HERC should discuss if limitations should be adopted on the retrospective continuous blood glucose monitoring for Type 1 diabetics as well.

Recommendations:

1. Keep 95250-95251 on Line 10 only
2. Place S1030 and S1031 on Line 10 only. Advise DMAP to remove these codes from the Ancillary List
3. Add a guideline note

A. OPTION 1

GUIDELINE NOTE XXX
Line 10

Real-time continuous blood glucose monitoring *(CPT codes 95250-1, HCPCS codes S1030-1)* is only included on Line 10 for Type 1 diabetics with HbA1c levels greater than 8.0% OR a history of recurrent hypoglycemia, AND for whom insulin pump management is being considered, initiated, or utilized.

Retrospective continuous glucose monitoring systems are covered for Type 1 diabetics.

B. OPTION 2
GUIDELINE NOTE XXX
Line 10

Continuous blood glucose monitoring *(CPT codes 95250-1, HCPCS codes S1030-1)* with real-time or retrospective continuous glucose monitoring systems are only included on Line 10 for Type 1 diabetics with HbA1c levels greater than 8.0% OR a history of recurrent hypoglycemia, AND for whom insulin pump management is being considered, initiated, or utilized.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: CONTINUOUS GLUCOSE MONITORING IN DIABETES MELLITUS

DRAFT AS REFERRED BY HTAS TO VBBS/HERC 11/26/2012

HERC COVERAGE GUIDANCE

Real-time continuous glucose monitoring systems should be covered for Type 1 diabetes mellitus patients with HbA1c levels greater than 8.0% or a history of recurrent hypoglycemia, for whom insulin pump management is being considered, initiated, or utilized.

Real-time continuous glucose monitoring systems should not be covered for Type 2 diabetes mellitus patients.

Retrospective continuous glucose monitoring systems should be covered for Type 1 diabetes mellitus and should not be covered for Type 2 diabetes mellitus.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCES

Langendam M, Luijf YM, Hooft L, DeVries JH, Mudde AH, Scholten RJPM. (2012). Continuous glucose monitoring systems for type 1 diabetes mellitus. *Cochrane Database of Systematic Reviews*, Issue 1. Art. No.: CD008101. DOI: 10.1002/14651858.CD008101.pub2. Retrieved from http://summaries.cochrane.org/CD008101/continuous-glucose-monitoring-systems-for-type-1-diabetes-mellitus

Golden, S.H., Brown, T., Yeh, H.C., Maruthur, N., Ranasinghe, P., Berger, Z., et al. (2012). Methods for Insulin Delivery and Glucose Monitoring: Comparative Effectiveness. Comparative Effectiveness Review No. 57. (Prepared by Johns Hopkins University Evidence-based Practice Center under Contract No. 290-2007-10061-I.) AHRQ Publication No. 12-EHC036-EF. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from www.effectivehealthcare.ahrq.gov/reports/final.cfm

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Diabetes mellitus (DM) is a metabolic disorder resulting from a defect in insulin secretion, insulin action, or both. A consequence of this is chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism. Long-term complications of DM include retinopathy, nephropathy and neuropathy, and the risk of cardiovascular disease is increased. There are several types of diabetes. In type 1 DM the body is unable to produce insulin and therefore people with this type are treated with insulin. Type 1 DM accounts for 10% of cases, is typically seen at onset in children and young adults (less than 30 years), and is often referred to as insulin dependent diabetes.

Self-monitoring of blood glucose (SMBG) is an essential part of diabetes management and is used to optimize glycemic control. Regular testing of blood glucose levels allows patients with diabetes to adjust insulin dosage appropriately, and is typically done using a finger capillary blood sample and a blood glucose meter several times per day. Continuous glucose monitoring (CGM) systems measure interstitial fluid glucose levels to provide semi-continuous information about glucose levels, which may identify fluctuations that would not be identified with self-monitoring alone. Continuous glucose monitoring is considered to be particularly useful for children (to reduce the often very high number of finger punctures in this group), for patients with poorly controlled diabetes, for pregnant women in whom tight glucose control is essential with respect to the outcome of pregnancy and for patients with hypoglycemia unawareness (to prevent dangerous episodes of hypoglycemia). There are two types of CGM systems:

- those that measure the glucose concentration during a certain time span, storing the information in a monitor that can be downloaded later

- real-time systems that continuously provide the actual glucose concentration on a display.

Continuous glucose monitoring can be used continuously or intermittently (e.g., a couple of days per month or in intervals of three days). Evaluation of blood sugar control is generally done by monitoring changes in HbA1c. A clinically significant change in this value is generally considered to be 0.5%.

Evidence Review

Cochrane Review

Children

Four out of the five randomized controlled trials (RCT) that evaluated retrospective CGM systems found that HbA1c levels decreased in both the CGM and SMBG group during follow-up, while one found that HbA1c level did not change in the CGM group but decreased in the SMBG group. The mean difference between the CGM group and the SMBG group in change in HbA1c ranged from -0.5% to 0.1%, but was not statistically significant in any of the five RCTs.

Severe hypoglycemia was measured in four studies. The occurrence of events was very low, and there were no significant differences between groups. Ketoacidosis was measured in one study, but again, the number of events was very small. The one RCT that measured quality of life found no significant differences between CGM and SMBG.

All three studies that evaluated real-time systems found that the HbA1c levels in both the CGM and SMBG group declined during the study period. Three months after baseline the difference in change was statistically significant in favor of CGM (change in HbA1c -0.5% versus -0.2%). At six months and 12 months follow-up, however, the difference in change in HbA1c level was no longer significant. Another outcome examined was the proportion of patients who improved their HbA1c level by at least 0.5%, which is generally considered a change that is clinically significant. When evaluating that outcome, the proportion of patients who improved their HbA1c level by at least 0.5% was significantly larger in the CGM group at three months and at six months after baseline. The occurrence of severe hypoglycemia after six months of follow-up was somewhat lower in the CGM study arm, but the difference was not statistically significant. Ketoacidosis events did not occur at six months follow-up and rarely after 12 months follow-up. The two studies that examined quality of life found small differences that were not statistically significant.

Adolescents

The two studies that included adolescents both used real-time CGM systems. In both studies the HbA1c levels in the CGM and SMBG group declined during the study, but the differences were not statistically significant, and by six months follow-up, the differences were even less. The proportion of patients that had improved their HbA1c level by at least 0.5% was equal in both groups. Severe hypoglycemic and ketoacidotic events were infrequent, and there were no significant differences between the groups.

The outcomes of quality of life, patient satisfaction, diabetes complications, CGM-derived glucose control, death and costs were not measured in any of the studies in adolescents.

Adults

Change in HbA1c level was measured in two RCTs addressing retrospective CGM, neither of which found a significant difference in change between the study arms. The one study that reported severe hypoglycemia found no difference between groups.

Five studies evaluated real-time CGM systems, and found that the change in decrease in HbA1c varied between -0.1% and -1.1%, with this change being statistically significant in three of them. The same pattern was seen six and 12 months after baseline, although the number of studies was fewer. In one study, sensor usage of more than 60% was associated with HbA1c reduction, and a larger proportion of patients improved their HbA1c by at least 0.5% in the CGM group. (Compliance with protocol is generally considered to be sensor usage at least 70% of the time. Compliance varies significantly among studies, with some studies of adolescents having sensor usage as low as 30%.) One study measured HbA1c levels after 18 months follow-up and found the overall difference between groups was insignificant. Four studies measured the occurrence of severe hypoglycemia. At three months, the number of events was very low, and at six and 12 months, the risk of severe hypoglycemia was increased for CGM users, but the difference was not statistically significant. The number of ketoacidosis events was very small.

Two studies measured quality of life after six months and found the differences between the CGM and SMBG group were small and not statistically significant. Two studies investigated patient satisfaction, one after three months and one after six months follow-up, although for both, patients in the CGM group were using an insulin pump, while the SMBG used multiple daily injections of insulin. Patients in the CGM group scored significantly higher on overall satisfaction. The outcomes of diabetes complications, death and costs were not measured in any of the studies in adults.

Pregnant women with diabetes type

The only study on pregnant women with diabetes did not present the data for type 1 and type 2 diabetes separately, so it is not presented here.

Subgroup analysis

There were no studies that included patients with hypoglycemia unawareness. For studies that were limited to patients with poorly controlled diabetes (HbA1c greater than 8.0%), three were for retrospective CGM systems and four for real-time CGM. For the retrospective CGM systems, the evidence for improved glycemic control is conflicting. Significantly lower, as well as significantly higher HbA1c levels for the CGM group at the end of the study were found, and a third RCT showed no effect at all. For real-time CGM systems, there is limited evidence for improved glycemic control, with a statistically and clinically significant effect in two of the four RCTs. These two had the largest mean differences in the change in HbA1c of all studies that measured this outcome (-1.12% and -0.6%).

Meta-analysis including all age groups
There was a statistically significant larger decline in HbA1c level for real-time CGM users starting insulin pump therapy compared to patients using multiple daily injections of insulin and SMBG (mean difference in HbA1c level change from baseline -0.7%). For patients where only the CGM was a new device, the average decline in HbA1c level was also statistically significantly larger for CGM users compared to the SMBG users. However, the decline was much smaller than in the group with the sensor-augmented insulin pump: the average difference change in HbA1c was 0.2%.There were no statistically significant differences in the risk of severe hypoglycemia or ketoacidosis.

[Evidence Source]

AHRQ Review

Evidence was identified evaluating the comparative effectiveness of real-time CGM versus SMBG in individuals with type 1 diabetes only. Compared with SMBG, real-time CGM achieved a lower HbA1c, with a mean between-group difference of -0.30 percent. Slightly greater reductions occurred where sensor compliance was 60 percent or greater (mean difference of -0.36 percent). There was no difference in the rate of severe hypoglycemia or quality of life. The evidence for other outcomes was low or insufficient. For CGM that is used in combination with an insulin pump, CGM achieved a greater reduction in HbA1c compared to multiple daily injections of insulin with SMBG, with a mean between-group difference of -0.68 percent. There was no difference in the rate of hypoglycemia, but the CGM group had significantly less hyperglycemia. There were no studies of the comparative effectiveness of real-time CGM versus SMBG in individuals with type 2 diabetes.

[Evidence Source]

Overall Summary

Retrospective CGMs are not more efficacious for any outcome, in any age group. There is some evidence that real-time CGM is more effective at decreasing HbA1c in children, although this does not appear to be the case for adolescents. In adults, there is also some evidence that real-time CGM is more effective at decreasing HbA1c, although not all studies were statistically significant. The study with the longest period of follow up (18 months) found no differences. In addition, the amount of decrease in HbA1c may not be clinically significant (less than 0.5%), with two exceptions: studies that compared CGM plus insulin pump to multiple daily injections of insulin plus SMBG, and studies of poorly controlled diabetics (HbA1c > 8.0%). Two studies found no differences in quality of life, while two found increased patient satisfaction in the insulin pump plus CGM group (compared to multiple daily injections of insulin plus SMBG). There is no evidence of a difference between CGM and SMBG in the incidence of hypoglycemia or ketoacidosis. There is no evidence that addresses the effect of CGM on diabetic complications, costs or mortality.

PROCEDURE

Continuous Glucose Monitoring

DIAGNOSES

Type 1 Diabetes Mellitus

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
250.x1	Diabetes Mellitus, type 1, not stated as uncontrolled
250.x3	Diabetes Mellitus, type 1, uncontrolled
ICD-9 Volume 3 (Procedure Codes)	
None	
CPT Codes	
83036	Hemoglobin; glycosylated (A1C)
83037	Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use
95250-1	Glucose monitoring by SQ device
97802- 97804	Medical nutrition therapy
98960-98962	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face, with the patient (could include caregiver/ family) each 30 minutes
99078	Physician educational services rendered to patients in a group setting (eg, prenatal, obesity, or diabetic instructions)
HCPCS Codes	
A4230-2	Insulin infusion pump supplies
A4233-6	Batteries for home blood glucose monitors
A4253	Blood Glucose test strips, box of 50
A4255	Platforms for home blood glucose monitor, 50/box
A4256	Calibrator solutions/chips
A4258	Spring-powered device for lancet, each
A4259	Lancets, per box of 100
A9274	External ambulatory insulin delivery system, disposable
A9276	Disposable sensor, CGM system
A9277	External transmitter, CGM system
A9278	External receiver, CGM system
E0607	Blood glucose monitor
E0784	Insulin infusion pump
E2100	Blood glucose monitor with voice synthesizer
E2101	Blood glucose monitor with integrated lancer
G0108-G0109	Diabetes outpatient self-management training services
G0270-G0271	Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease)
S1030-1	Continuous non-invasive glucose monitoring device, purchase/rental
S9140	Diabetic management program, follow-up visit to non-MD provider
S9141	Diabetic management program, follow-up visit to MD provider

Note: Inclusion on this list does not guarantee coverage

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

HERC Coverage Guidance – Continuous Glucose Monitoring in Type One Diabetes Mellitus
Disposition of Public Comments

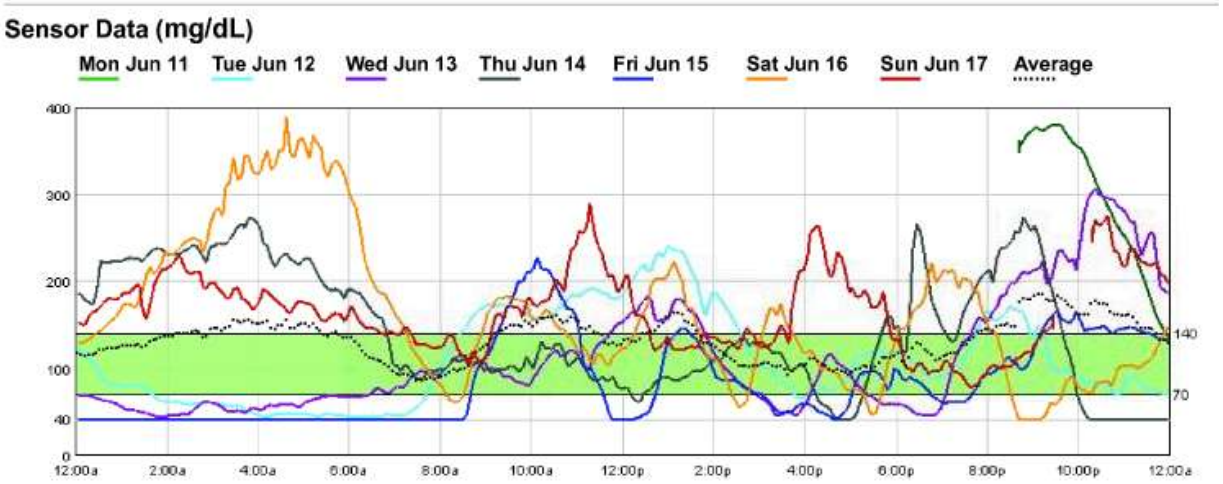
General Comments

Stakeholder	#	Comment	Disposition
Medtronic Diabetes Northridge, CA	1	On behalf of Medtronic Diabetes, I am pleased to submit this response to the Oregon Health Evidence Review Commission and Health Technology Assessment Subcommittee with respect to the Draft Coverage Guidance on Continuous Glucose Monitoring. Medtronic appreciates the work Oregon HERC and HTAS has put forth this far to draft Coverage guidance for Continuous Glucose Monitoring.	Thank you for taking the time to comment.
	2	Based on the compelling and continually expanding data and trial results supporting the clinical value of CGM for patients with diabetes, we are in support of the draft guidance recommended at the June 25th meeting for Personal/Real-Time CGM. The guidance states that Personal/Real-Time CGM "should be covered for Type 1 diabetes mellitus patients with a history of recurrent hypoglycemia or HbA1c >8 for whom insulin pump management is being considered, initiated, or utilized.	Thank you for your comment.
	3	Medtronic however, does not agree with the recommendation on Retrospective (Professional) CGM. We do suggest that this device should be covered. Retrospective CGM provides Health Care Providers significant and meaningful insight to glucose patterns that otherwise would not be available. Health Care Providers utilize the data to help guide therapy, modify treatment regimens, and teach patients how food, activity, and personal involvement impacts their ability to better manage their disease. In addition, by not continuing to cover professional services (95250 and 95251) it would create disparity of care for the patients served in Oregon. All other payer entities in the state of Oregon including Medicare and all private/commercial payers including United Healthcare, Aetna, Cigna, Humana, Health Net, and Wellpoint/Anthem have coverage and payment for Retrospective CGM. We strongly urge HERC to continue to maintain coverage on line 10 of the Prioritized List of Services for Type 1 diabetes, and recommend that it be included for any insulin treated diabetes patient	The evidence source did not find a statistically significant difference in HbA1c levels or hypoglycemia in any trial that compared a retrospective CGM to control. The HTAS makes its decisions based on evidence of effectiveness and harms, not on the basis of other payers' coverage policies.
	4	**Professional (Retrospective) CGM** **95250** Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording **95251** Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report	HTAS is aware of these CPT codes.
	5	Studies have shown that retrospective CGM detects glycemic excursions that were missed with SMBG and is particularly well suited to detecting asymptomatic hypoglycemia. CGM detected a longer duration of hypoglycemia than SMBG[1] and identified episodes of postprandial hyperglycemia[2, 3, 4] nocturnal hypoglycemia[5, 6, 7, 8] and asymptomatic hypoglycemia[9, 10] that were frequently not identified by SMBG. In a study of elderly individuals with well-controlled Type 2 diabetes, CGM captured 103 episodes of hypoglycemia in 20 patients over four 72-hour periods of monitoring and detected elevated postprandial glucose levels after 57% of meals.[11] None of the hypoglycemic episodes detected by CGM, many of which occurred at night, were recorded in patients' diaries. CGM is the best tool for detecting episodes of asymptomatic and nocturnal hypoglycemia, both of which	The citations listed were published before the date of the Cochrane review (last search date June 2011). The HTAS bases their guidance documents on reviews of the literature that utilize the highest standards of evidence based medicine. Studies are included or

Stakeholder	#	Comment	Disposition
		tend to occur more frequently in patients who have hypoglycemia unawareness.[12]	excluded based on transparent, reproducible criteria; therefore the HTAS does not investigate individual studies. The HTAS assumes that the conclusions reached by the authors of these reviews weigh all the available evidence in accordance with the principles of evidence based medicine, and does not attempt to re-review the entire body of evidence to reach its own conclusions.
	6	Studies document the following benefits of CGM: • CGM detects glycemic excursions missed with SMBG. Studies have shown that CGM detects glycemic excursions that were missed with SMBG and is particularly well suited to detecting asymptomatic hypoglycemia. CGM detected a longer duration of hypoglycemia than SMBG, [13] and identified episodes of postprandial hyperglycemia, [14, 15, 16] nocturnal hypoglycemia, [17, 18, 19, 20] and asymptomatic hypoglycemia[21, 22] that were frequently not identified by SMBG. CGM is the best tool for detecting episodes of asymptomatic and nocturnal hypoglycemia, both of which tend to occur more frequently in patients who have hypoglycemia unawareness.[23]	Assuming commenter is referring to retrospective CGM, see comment #5
	7	• CGM improves diabetes management. The identification of glycemic excursion patterns can be used to reduce the incidence of hyperglycemia and hypoglycemia by making changes to patients' diabetes management plans, including 1) altering the insulin-to-carbohydrate ratio, 2) altering the basal insulin regimen, 3) using glucose tablets instead of food or juice to treat hypoglycemia, 4) reducing the amount of supplemental insulin needed to correct elevated blood glucose values, and 5) changing patients' approaches to exercise. [24, 25]	Assuming commenter is referring to retrospective CGM, see comment #5
	8	• CGM improves diabetes outcomes. A substantial body of research has demonstrated that use of CGM by both adults and children can decrease A1C.[26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36]	Assuming commenter is referring to retrospective CGM, see comment #5
	9	Evidence of CGM benefits is further reflected in professional standards. The AACE Medical Guidelines for Clinical Practice for the Management of Diabetes Mellitus include the following recommendation on use of CGM in type 1 diabetes: • Arrange for continuous glucose monitoring for patients with T1DM with unstable glucose control and for	HTAS does not disagree with the use of CGM. The guideline referenced by the commenter does not specify that CGM should be retrospective.

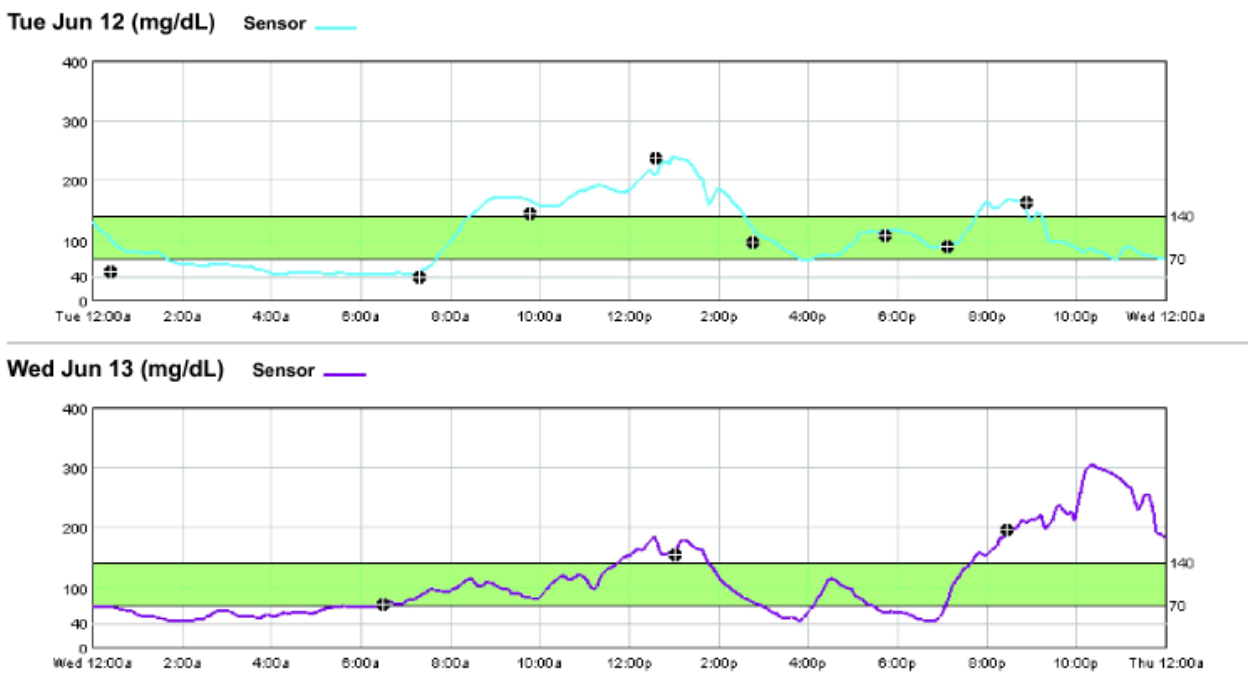
Stakeholder	#	Comment	Disposition
		patients unable to achieve an acceptable HbA1C level; continuous glucose monitoring is particularly valuable in detecting both unrecognized nocturnal hypoglycemia and postprandial hyperglycemia.[37]	
	10	The ADA's Standards of Medical Care in Diabetes - 2012 make the following CGM recommendations (Levels "A", "C", and "E", respectively)[38]: • Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults (age > 25 years) with type 1 diabetes. (A) • Although the evidence for A1C lowering is less strong in children, teens, and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. • CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes.	See comment #9
	11	We hope that Oregon Health Authority finds this information useful in evaluating the benefits of continuous glucose monitoring technology. Should you have any questions regarding this information, please contact me.	Thank you for your comment.
Physician, Associate Professor Portland, OR	12	The purpose of this letter is to provide my opinion on the Draft Coverage Guidance on Continuous Glucose Monitoring by the Oregon Health Evidence Review Commission and Health Technology Assessment Subcommittee. Based on several clinical trials regarding the use of CGM in patients with diabetes, I am in full support of the draft guidance recommended at the June 25th meeting for Personal/Real-Time CGM. The guidance states that Personal/Real-Time CGM "should be covered for Type 1 diabetes mellitus patients with a history of recurrent hypoglycemia or HbA1c >8 for whom insulin pump management is being considered, initiated, or utilized.	Thank you for taking the time to comment.
	13	I am a specialist in diabetes and I see patients at the [*clinic name removed*] diabetes clinic. I believe that such a policy will help to minimize hypoglycemia and hyperglycemia in persons with type 1 diabetes, will minimize acute and chronic complications, and will thus improve their short-term and long-term quality of life.	Thank you for your comment.
JDRF Washington, DC	14	JDRF applauds the efforts of Health Technology Assessment Subcommittee (HTAS) in developing the draft guidance on CGM for Type 1 Diabetes. As JDRF's previous letter of June 21, 2012 to the HTAS indicates, we support broad coverage of CGM for those with type 1 diabetes (T1D), based on the extensive evidence of clinical benefit, the recommendations of all leading diabetes clinical care guidelines, and data on cost effectiveness. The Subcommittee's proposed draft guidance states that Personal/Real-Time CGM should be covered for Type 1 diabetes mellitus patients with a history of recurrent hypoglycemia or HbA1c >8 for whom insulin pump management is being considered, initiated, or utilized'. We believe this language is consistent with the clinical trial data from the 2006 JDRF funded trial and the series of published papers detailing the findings of the trial since 2008 highlighting the clinical effectiveness of CGM.	Thank you for taking the time to comment.
	15	JDRF however, has concern with the recommendation that retrospective (professional) CGM devices should not be covered and respectfully suggests that this language be reconsidered. We believe that retrospective CGM provides clinicians with critical insight to glucose excursions that otherwise would not be available. Patients'	The evidence source did not find a statistically significant difference in HgA1c levels or hypoglycemia in any

Stakeholder	#	Comment	Disposition
		doctors utilize the data to help guide therapy, modify treatment regimens, and teach patients how food, activity, and personal involvement impacts their ability to better manage their disease.	trial that compared a retrospective CGM to control.
	16	In addition, eliminating coverage would create disparity of care for the patients served in Oregon. All other payer entities in the state of Oregon including Medicare and all private/commercial payers including United Healthcare, Aetna, Cigna, Humana, Health Net, and WellPoint/Anthem have coverage and payment for Retrospective CGM. Thank you again for consideration of our comments.	The HTAS makes its decisions based on evidence of effectiveness and harms, not on the basis of other payers' coverage policies.
Physician, Director of a diabetes health center Portland, OR	17	Thank you for your efforts in developing the guidance document on continuous glucose monitoring. I also greatly appreciated the opportunity to address the group at your meeting in June. I agree with your recommendations concerning the real-time continuous glucose monitoring systems. This is an important tool in the care of patients with type 1 diabetes that would be used sparingly and selectively to the benefit of appropriate subjects.	Thank you for taking the time to comment.
	18	During the June meeting I did not have time to comment on retrospective CGM. The guidance document refers to the lack of evidence for benefit and recommends against coverage for this tool. Although it is true that RCTs have not clearly shown benefit of retrospective CGM with regard to A1c reduction, for those of us who have used it, experience says it is a very important tool for some patients. I believe the manufacturers have not promoted extensive research in this are because the focus has been on real-time CGM. Nevertheless, most payers including Medicare have readily recognized the value of this technology. The cost is relatively low. There is plentiful evidence that CGM will identify unrecognized glucose fluctuations and hypoglycemia. The concept and intent are different than when using real-time CGM. Real-time CGM helps patients make moment-to-moment decisions on glucose values and trends as well as offering education when used to review the tracings. The emphasis with retrospective CGM is on identification of patterns that can be used by the provider to educate patients and to make safe adjustments in insulin. Most importantly, it identifies unrecognized hypoglycemia that is potentially life threatening. This is particularly important considering the fact that hypoglycemia is thought to be one of the leading causes of death in young individuals with type 1 diabetes. I have personally experienced at least a half-dozen patient deaths due to hypoglycemia and many others who have had severe injuries and other major consequences.	HTAS appreciates the concern about hypoglycemia, however, the evidence source did not find a significant difference in episodes of hypoglycemia in any trial that compared a retrospective CGM to control.
	19	Sometimes a single picture is worth a thousand words so I am including the following images from a retrospective CGM tracing done several days prior to the June meeting on a 30 year old teacher who was not aware of more than rare nocturnal hypoglycemia: [*Graph located on next page*]	While anecdotal experience has a strong influence on individual opinion, it is inherently susceptible to bias. High quality RCTs are the best way to assess true treatment effects, and the evidence examined by HTAS does not support the efficacy of retrospective CGM.

Stakeholder	#	Comment	Disposition
			

	Mon Jun 11	Tue Jun 12	Wed Jun 13	Thu Jun 14	Fri Jun 15	Sat Jun 16	Sun Jun 17	Average / Total
# Sensor Values	40	288	288	288	288	288	279	1,759
Highest	380	240	306	274	227	389	290	389
Lowest	135	43	44	40	40	40	78	40
Average	297	110	111	144	83	163	165	133
Standard Dev.	79	53	66	69	49	83	45	74
MAD %	2.1	22.5	8.4	21.5	27.6	11.2	6.5	17.3
Correlation	N/A	0.96	0.99	0.94	0.74	N/A	1.00	0.96
# Valid Calibrations	2	8	3	4	7	5	4	33
Designation	X				X			

X: Use Clinical Judgment S: No Sensor Data C: No Calibration BG's

Stakeholder	#	Comment	Disposition
	20		See comment #19
	21	This type of tracing is paired with a diary to indicate food intake, activity, insulin doses and other relevant events. As you can see, this patient had highly significant nocturnal hypoglycemia (< 50 mg/dl) on 3 of the 7 days tested by a retrospective sensor. She had no symptoms on any of these nights. It was frightening to find that she remained at dangerous levels of hypoglycemia for many hours during the night. This was definitely life-threatening and led to significant reductions in her insulin pump basal rates at night despite the fact that they were already much lower than daytime rates. I would like to think we avoided what would otherwise have been an eventual seizure or even a potential fracture falling out of bed or worst case, an arrhythmia.	See comment #19
	22	This is just one of many cases where findings on a retrospective CGM study resulted in important changes in therapy to improve safety or glucose control. In fact, I would estimate that >95% of such studies guide the provider to change insulin or behaviors to the benefit of the patient.	Thank you for providing your clinical opinion.
	23	Trying to help relate retrospective CGM to other common, covered procedures, I would have you consider ECGs, PFTs or possibly sleep studies. My guess is that ECGs in asymptomatic patients have never been shown to reduce the frequency of cardiac events by today's standards of evidence. Likewise, while PFTs can identify problems and guide therapy, they have likely never been subjected to RCT to show they directly improve outcomes.	HTAS has not reviewed the evidence on ECGs or PFTs, but would require the same rigorous evaluation if they did.

Stakeholder	#	Comment	Disposition
	24	I would be happy to provide literature to highlight studies showing identification of unrecognized long exposure to hypoglycemia if requested by the committee. The fact that most attention and studies have focused on real-time CGM speaks more to the business plans of device companies than to the potential advantage for patient care. Although you may want to restrict the use to specific situations and only with a limited frequency, I believe this is a tool that will not be costly and will serve patients and experienced type 1 diabetes providers well. Please consider a change in your recommendations.	Thank you for your comment. HTAS appreciates that impact of business on driving the research agenda, but notes that the evidence is not entirely lacking for retrospective CGM, with 7 studies in the evidence source.
Citizen/Patient Portland, OR	25	I am writing in response to the proposed coverage guidance for continuous glucose monitoring (CGM) use by people with Type 1 diabetes. I applaud your proposed coverage of CGM for people who are having trouble bringing their HbA1c below 8.0 and for recurrent hypoglycemia. The use of a CGM has been repeatedly shown to help improve blood sugar control and lower HbA1c values. However, as a diabetic for over 15 years, and the father of a child with diabetes since age 5 (now 21), I can tell you that long term blood glucose control is only one (albeit very important) measure of successfully managing Type 1 diabetes. Equally important measures are the ability to reduce or eliminate dangerous high blood sugars, severe low blood sugars, the forewarning of potential ketoacidosis, effective sick day management, and finally, quality of life (the ability to sleep well without worrying about undetected hypoglycemia, for instance).	Thank you for taking the time to comment.
	26	CGM use can aid in weight management and exercise by allowing more confidence that lack of eating or heavy/prolonged exercise will result in severe lows. Importantly, where the proposed guidance is concerned, these benefits are equally important to those who have consistently maintained an HbA1C below 8.0 as to those whose HbA1c is above 8.0.	Thank you for sharing your opinion. HTAS believes the importance of lowering HbA1c is greater in patients with levels > 8.0.
	27	Although hypoglycemia is rightly cited as a reason for including coverage for CGM use, the absence of recorded hypoglycemic events should not be a reason to deny coverage for those with high or low HbA1c values. First, there is good evidence that many Type 1 diabetics do not capture the occurrence of many low blood sugar events through standard blood glucose monitoring: Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group - Prolonged Nocturnal Hypoglycemia Is Common During 12 Months of Continuous Glucose Monitoring in Children and Adults With Type 1 Diabetes. *Diabetes Care May 2010 33:1004-1008*	HTAS does not debate the fact that diabetes do not capture many low blood sugar events. The Cochrane review identified four studies that measured the occurrence of severe hypoglycemia. At three months, the number of events was very low, and at six and 12 months, the risk of severe hypoglycemia was actually increased for CGM users, but the difference was not statistically significant.
	28	Those who are able to successfully use a CGM to either better control their diabetes, resulting in a lower HbA1c and avoiding recurrent hypoglycemia (the two qualifying criteria), should not be dropped from coverage of CGM	The guidance does not address cessation of coverage, only

Stakeholder	#	Comment	Disposition
		use due to that success.	indications for initiation.
	29	The single study referenced in the guidance focused primarily on "average blood glucose level" as expressed in the measured HbA1c. Although mentioning the importance of hypoglycemia (and an attempt to measure the occurrence) it was not deemed significant due to the low number of events which precluded their evaluation. There are other studies however, that have confirmed the benefits of CGM use in patients with well controlled glucose (HbA1c < 7.0) and in those with poorly controlled diabetes in terms of avoiding severe or prolonged hypoglycemia:	It is not clear what single study the commenter is referring to. The guidance references the Cochrane review which is a full systematic review of the evidence and includes a total of 22 studies.
	30	"An additional important observation was the remarkably low rate of severe hypoglycemic events during the extension phase of the study. The rate of severe hypoglycemia in our CGM subjects with a mean A1C of 6.8% during the 6-month extension phase was markedly lower than the rate of severe hypoglycemia in the Diabetes Control and Complications Trial (DCCT) intensive treatment group, which had mean A1C of 7.1% (7 vs. 62 events per 100 person-years) (6). The total absence of severe hypoglycemia during the second 6 months of the study in the subjects who had a baseline A1C <7.0% is particularly striking, especially because these subjects were able to maintain a mean A1C of 6.4%. It is possible that the decline in severe hypoglycemic events during the second 6 months of the study resulted from learning from prior experience, including appropriate setting of the low alarms, glucose targets, and titration of basal and bolus insulin doses. It is also intriguing to speculate that the reduction in exposure to biochemical hypoglycemia over the 12 months of the study may have protected subjects from severe hypoglycemic events by enhancing their counterregulatory hormone defense mechanisms against hypoglycemia (7)." The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group - Sustained Benefit of Continuous Glucose Monitoring on A1C, Glucose Profiles, and Hypoglycemia in Adults With Type 1 Diabetes. *Diabetes Care November 2009 32:2047-2049*	The citations listed were published before the date of the Cochrane review (last search date June 2011). The HTAS bases their guidance documents on reviews of the literature that utilize the highest standards of evidence based medicine. Studies are included or excluded based on transparent, reproducible criteria; therefore the HTAS does not investigate individual studies. The HTAS assumes that the conclusions reached by the authors of these reviews weigh all the available evidence in accordance with the principles of evidence based medicine, and does not attempt to re-review the entire body of evidence to reach its own conclusions.
	31	We are only beginning to understand all the benefits of tight glucose control and the effects of hypoglycemia on the body, and some studies point to a possible link to development of atherosclerosis. Marga Giménez, Rosa Gilabert, Joan Monteagudo, Anna Alonso, Roser Casamitjana, Carles Paré, and Ignacio Conget - Repeated Episodes of Hypoglycemia as a Potential Aggravating Factor for Preclinical Atherosclerosis in Subjects With Type 1 Diabetes. *Diabetes Care January 2011 34:198-203*	See comment #30
	32	As a CGM user for approximately 2 years, I can tell the HERC that the use of a CGM has made my day to day life with diabetes more predictable, more successful, and more enjoyable. I believe that the use of a CGM has	Thank you for sharing your

Stakeholder	#	Comment	Disposition
		reduced the likelihood that I would end up in the hospital for dehydration during sick days (ketones with low blood sugar being a surprising and challenging situation to deal with) and allowed me to be a more confident and successful public servant. I believe that every person with Type 1 diabetes should be encouraged to use a CGM if they have a need, the inclination, and the motivation.	perspective.
	33	For these reasons, I believe the use of a CGM is warranted and beneficial for all with Type 1 diabetes in terms of safety, in terms of quality of life and in terms of long term health benefits and saving of health care costs. The coverage of CGM use should be possible regardless of whether one's HbA1c is above or below 8.0, or their success in avoiding (and success in documenting) recurrent hypoglycemia. Thank you for considering these comments.	Thank you for sharing your perspective.
	34	Please note there are typos on pages 2 and 4 of the proposed guidance where HbA1c is mistakenly shown as HgA1c or HgbA1c.	Thank you, typos have been corrected.
American Diabetes Association Oregon Office Portland, OR	35	The American Diabetes Association (Association) is pleased to provide additional comments to the Commission regarding the Draft Coverage Guidance on Continuous Glucose Monitoring (CGM) in Type 1 Diabetes, **and** to address particular questions posed by members of the Commission to the Association during the June 25 hearing. We appreciate your willingness to consider additional information from the Association before revising the Coverage Guidance for Self-Monitoring of Blood Glucose (SMBG) for Type 1 and Type 2 Diabetes, and we are pleased to respond to your request. [***Comments regarding SMBG will be addressed in a separate disposition***.]	Thank you for your comments.
	36	**V. Comments in response to the Draft Coverage Guidance: Continuous Glucose Monitoring in Type 1 Diabetes Mellitus issued on July 10, 2012** The Association's *Standards of Medical Care in Diabetes – 2012* includes the following recommendations: • CGM in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults age 25 and over with type 1 diabetes. • Although the evidence for A1C-lowering is less strong in children, teens and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. • In addition, CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes.	HTAS believes that the current coverage guidance supports these stated standards.
	37	The revised Draft Coverage Guidance on Continuous Glucose Monitoring in Type 1 Diabetes issued on July 10 includes the following recommendation: Real time CGM systems should be covered for Type 1 diabetes mellitus patients with a history of recurrent hypoglycemia or HbAlc > 8% for whom insulin pump management is being considered, initiated or utilized. We note that research has shown benefits for CGM in individuals with type 1 diabetes on intensive insulin therapy (*either* an insulin pump or multiple daily injections).[3] ***Thus, we recommend adding "multiple daily insulin injections or" after the words "for whom" in the Coverage Guidance document to include individuals on multiple daily injections of insulin.***	HTAS acknowledges that CGM has been shown to have a statistically significant beneficial effect on HbA1c in both insulin pump and MDI populations, however, the improvements in HbA1c are generally not considered clinically significant in the MDI patients (-

Stakeholder	#	Comment	Disposition
			0.30% to -0.36%), and there have been no studies that found improvements in quality of life, hypoglycemia, diabetic complications or mortality in this patient population.
	38	Diabetes is a complex disease to manage and can lead to short and long term complications. The goal of diabetes care is to avoid the devastating and costly complications of the disease. The costs associated with diabetes, including diagnosed and undiagnosed diabetes, prediabetes, and gestational diabetes, and their complications, accounted for $218 billion in direct and indirect costs in 2007 alone. Much of the economic burden of diabetes is related to its complications including blindness, amputation, kidney failure, heart attack, and stroke. Yet, we have made major strides in effectively managing diabetes and reducing the risk for these devastating – and costly – complications through necessary medical care, medications and other tools, patient self-management, education, and support. We appreciate the opportunity to provide comments to the Commission as it develops Coverage Guidance documents for CGM and SMBG. The Association looks forward to reviewing the revised Coverage Guidance documents.	HTAS is aware of the complexity of diabetes management, and believes that the guidance as currently written provides the needed flexibility in patient management. Thank you for taking the time to provide the HTAS with this information.

HERC Coverage Guidance – Continuous Glucose Monitoring in Diabetes Mellitus
Disposition of Public Comments – Second Posting

General Comments

Stakeholder	#	Comment	Disposition
American Diabetes Association Oregon Office Portland, OR	1	On behalf of the people with diabetes in Oregon, the American Diabetes Association (Association) is pleased to provide additional comments to the Commission regarding the revised *Draft Coverage Guidance on Continuous Glucose Monitoring (CGM) in Diabetes Mellitus*. The Association's *Standards of Medical Care in Diabetes – 2012* includes the following recommendations: • CGM in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults age 25 and over with type 1 diabetes. • Although the evidence for A1c-lowering is less strong in children, teens and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. • In addition, CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes.	Thank you for taking the time to comment. HTAS is aware of ADA recommendations.
	2	The revised *Draft Coverage Guidance on Continuous Glucose Monitoring in Diabetes Mellitus* issued on September 24 includes the following recommendation: Real time CGM systems should be covered for Type 1 diabetes mellitus patients with HbAlc > 8% or a history of recurrent hypoglycemia or for whom insulin pump management is being considered, initiated or utilized, and should not be covered for individuals with type 2 diabetes mellitus. Research has shown benefits for CGM in individuals with type 1 diabetes on intensive insulin therapy, through *either* an insulin pump or multiple daily injections.[1] ***As such, we recommend anyone on multiple doses of insulin or continuous subcutaneous insulin infusion with recurrent hypoglycemic episodes or persistently high HbA1c levels be given the option of real-time CGM***. [1] Tamborlane WV, Beck RW, Bode BW, et al.; Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. N Engl J Med 2008;359:1464-1476.	The citations listed were published before the date of both evidence reviews (last search dates June and July 2011). The HTAS bases their guidance documents on reviews of the literature that utilize the highest standards of evidence based medicine. Studies are included or excluded based on transparent, reproducible criteria; therefore the HTAS does not investigate individual studies. The HTAS assumes that the conclusions reached by the authors of these reviews weigh all the available evidence in accordance with the principles of evidence based medicine, and does not attempt to re-review the entire body of evidence to reach its own conclusions. Both evidence sources found significantly greater improvement in HbA1c in patients using insulin pumps than in those using multiple daily injections,

Stakeholder	#	Comment	Disposition
			and no difference in risk of severe hypoglycemia.
	3	Diabetes is a complex disease to manage and can lead to short and long term complications. The goal of diabetes care is to avoid the devastating and costly complications of the disease. The costs associated with diabetes, including diagnosed and undiagnosed diabetes, prediabetes, and gestational diabetes, and their complications, accounted for $218 billion in direct and indirect costs in 2007 alone. Much of the economic burden of diabetes is related to its complications including blindness, amputation, kidney failure, heart attack, and stroke. Yet, we have made major strides in effectively managing diabetes and reducing the risk for these devastating – and costly – complications through necessary medical care, medications and other tools, patient self-management, education, and support. We appreciate the opportunity to provide comments to the Commission as it develops the Coverage Guidance document for CGM.	HTAS is aware of the implications and costs of diabetes. Thank you for your comment.

CG - Diagnosis of sleep apnea in adults

Question: How should the Coverage Guidance - *DIAGNOSIS OF SLEEP APNEA IN ADULTS* be applied to the Prioritized List?

Question source: Health Technology Assessment Subcommittee

Current Prioritized List Status:

Line: 210
Condition: SLEEP APNEA AND NARCOLEPSY (See Guideline Notes 1,27,36,64,65,76)
Treatment: MEDICAL AND SURGICAL TREATMENT
ICD-9: 278.03,327.20-327.21,327.23-327.29,347.00-347.01,780.51,780.53,780.57
CPT: 21193-21235,30117,30140,30520,31600-31610,31820,31825,42140-42160,42820-42836,96150-96154,98966-98969,99051,99060,99070,99078,99201-99360,99366,99374,99375,99379-99412,99429-99444,99468-99480,
99605-99607
HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,S0270-S0274

GUIDELINE NOTE 27, SLEEP APNEA
Line 210
Surgery for sleep apnea for adults is only covered after documented failure of both CPAP and an oral appliance.

Coverage Guidance Box:

The following diagnostic tests for Obstructive Sleep Apnea (OSA) should be covered for adults:
1. Type I PSG is covered when used to aid the diagnosis of OSA in patients who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
2. Type II or Type III sleep testing devices are covered when used to aid the diagnosis of OSA in patients who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
3. Type IV sleep testing devices measuring three or more channels, one of which is airflow, are covered when used to aid the diagnosis of OSA in patients who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
4. Sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are covered when used to aid the diagnosis of OSA in patients who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

Background on Types of OSA testing
Methods of Measurement
Diagnosing OSA by detailing obstructive episodes is done using a variety of types of monitors in either the laboratory or home setting, and are categorized as follows:

- Type I: PSG in sleep facility

- Type II: Portable recording; same information as Type I (3 sleep arousal channels and minimum of 2 respiratory information channels)
- Type III: Portable recording; minimum of 2 respiratory channels (with no channels which differentiate waking and sleeping)
- Type IV: Portable monitors that fail Type III criteria

HERC Staff Recommendations:

1) Adopt a new Diagnostic Guideline

DIAGNOSTIC GUIDELINE XX DIAGNOSTIC TESTING FOR OBSTRUCTIVE SLEEP APNEA (OSA)

The following diagnostic tests for OSA are covered for adults:
1. Type I PSG is covered when used to aid the diagnosis of OSA in patients who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
2. Type II or Type III sleep testing devices are covered when used to aid the diagnosis of OSA in patients who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
3. Type IV sleep testing devices measuring three or more channels, one of which is airflow, are covered when used to aid the diagnosis of OSA in patients who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
4. Sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are covered when used to aid the diagnosis of OSA in patients who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

Code	Code Description	Current Placement	Recommended Placement
95800	Sleep study, unattended, simultaneous recording: heart rate, O2 sat, respiratory analysis, sleep time	DMAP Diagnostic File	DMAP Diagnostic File
95801	Sleep study, unattended, simultaneous recording: heart rate, O2 sat, respiratory analysis	DMAP Diagnostic File	DMAP Diagnostic File
95803	Actigraphy	DMAP Excluded File	**No change. This appears to be actigraphy alone, not a device measuring 3 or more channels.**
95805	Multiple sleep latency test	DMAP Ancillary Codes File	**The utility of this not determinable through this coverage guidance. No**

			specific recommendation to DMAP.
95806	Sleep study, unattended, simultaneous recording: heart rate, O2 sat, respiratory airflow and effort	DMAP Ancillary Codes File	DMAP Diagnostic File
95807	Sleep study,simultaneous recording: ventilation, respiratory effort, ECG or heart rate, O2 sat, attended by technologist	DMAP Ancillary Codes File	DMAP Diagnostic File
95808	Polysomnography: sleep staging with 1-3 additional parameters, attended by technologist	DMAP Ancillary Codes File	DMAP Diagnostic File
95810	Polysomnography: sleep staging with 4 or more additional parameters, attended by technologist	DMAP Ancillary Codes File	DMAP Diagnostic File
95811	Polysomnography: sleep staging with 4 or more additional parameters, with initiation of CPAP, attended by technologist	DMAP Ancillary Codes File	DMAP Diagnostic File
G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation	DMAP Ancillary Codes File	DMAP Diagnostic File
G0399	Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation	DMAP Diagnostic Procedure File	DMAP Diagnostic File
G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels	DMAP Ancillary Codes File	DMAP Diagnostic File

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: DIAGNOSIS OF SLEEP APNEA IN ADULTS

DRAFT AS REFERRED BY HTAS TO HERC 11/26/2012

HERC COVERAGE GUIDANCE

The following diagnostic tests for Obstructive Sleep Apnea (OSA) should be covered for adults:

1. Type I PSG is covered when used to aid the diagnosis of OSA in patients who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.

2. Type II or Type III sleep testing devices are covered when used to aid the diagnosis of OSA in patients who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

3. Type IV sleep testing devices measuring three or more channels, one of which is airflow, are covered when used to aid the diagnosis of OSA in patients who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

4. Sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are covered when used to aid the diagnosis of OSA in patients who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Heath Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Healthcare Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

EVIDENCE SOURCE

Gleitsmann, K., Kriz, H., Thielke, A., Bunker, K., Ryan, K., Lorish, K., & King, V. (2012). *Sleep apnea diagnosis and treatment in adults.* Produced for the Washington HTA Program. Olympia, WA: Center for Evidence-based Policy, Oregon Health and Science University for the Washington Health Technology Assessment Program. Retrieved September 13, 2012, from http://www.hta.hca.wa.gov/documents/sleep_apnea_final_report.pdf

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Obstructive sleep apnea (OSA) refers to sleep-disordered breathing due to the recurrent collapse of pharyngeal tissues resulting in snoring, fitful sleep, and daytime somnolence. These episodes are characterized by either reduced airflow (hypopnea), or a complete obstruction (apnea), with a subsequent drop in oxygen saturation, interfering with gas exchange. Obstructive sleep apnea is a cause of significant morbidity and mortality and is associated with hypertension, neuropsychological impairment, motor vehicle accidents, stroke, cardiovascular disease, diabetes, and decreased quality of life. The prevalence of OSA is 2% to 7% in the general adult population. Prevalence increases steadily with age, to approximately 20% among people older than age 60.

Risk factors for OSA include male gender, age, obesity, airway characteristics, familial/genetic predisposition, smoking, and alcohol consumption. The majority of patients with OSA are asymptomatic, unaware of their sleep disordered breathing and associated health risks.

The diagnosis as well as the treatment of OSA is complicated by the difficulty in defining the syndrome. There is controversy surrounding the parameters to be used in a clinical definition as well as which diagnostic method is most appropriate to detect OSA. The current standard for diagnosing OSA is polysomnography (PSG) administered in a sleep study facility. The frequency of obstructed breathing events (i.e., the apnea-hypopnea index (AHI)), combined with multiple other clinical features of obstruction (e.g., oxygen desaturation, air flow, choking episodes) are recorded during

sleep. A diagnosis of OSA is generally made when AHI is greater than or equal to 15 or greater than 5 with noticeable daytime symptoms. Considerable costs and patient inconvenience are involved in a PSG study. Portable PSG monitors, various questionnaires, and predictive models using anatomic and demographic variables have been developed to aid in screening candidates for referral for further diagnostic testing (e.g., sleep lab PSG).

Evidence Review

Diagnosing OSA: The "Gold Standard"
Most experts consider laboratory-based PSG to be the reference standard for measuring Apnea-Hypopnea Index (AHI) in order to diagnose OSA. However, there are significant challenges that can be raised in considering PSG to be the "gold standard". This would imply that this test is essentially error-free and therefore has the ability to prognosticate patients diagnosed with OSA from those without OSA. No current established threshold level for AHI exists that indicates the need for treatment. Furthermore, several facets raise uncertainty regarding PSG's place as the diagnostic "gold standard":

- There are variations across laboratories in the definitions of OSA (using different thresholds of AHI, from 5 to 15 events/hr) and in the way that the PSG results are read and interpreted.
- Apnea-Hypopnea Index, which is used as the single metric to define OSA, can vary from night to night and does not take into account symptoms, comorbidities, or response to treatment.
- Apnea-Hypopnea Index has variable value as a predictor of clinical outcomes:
    - The strength of evidence is high (based on four trials) that high baseline (AHI>30 events/hr or range) AHI is a strong and independent predictor of all-cause mortality over several years of follow-up (2-14 years).
    - The association between baseline AHI and the other long-term clinical outcomes is less robust, having been analyzed by only one or two studies:
        - Cardiovascular (CV) disease (studies reported mixed results regarding CV death, but AHI >30 was an independent predictor of nonfatal CV disease.
        - Stroke (one study suggested that the association between AHI and stroke may be confounded by obesity).
        - Hypertension (studies had uncertain conclusions regarding the possible association between AHI and incident hypertension)
        - Non-insulin-dependent diabetes and other metabolic abnormalities (studies reported mixed results that suggested an association between AHI and incident type 2 diabetes which, in one study, was confounded by obesity)
        - Decreased quality of life (a single study found no significant association between AHI and future quality of life [SF-36 after 5 years]).

- No current established threshold level for AHI exists that indicates the need for treatment.

In addition to the uncertainty surrounding the clinical utility of the AHI, the measurement of this index is also subject to several sources of variability. Airflow measurements are assessed by different instruments between laboratories and are subject to variation depending on the extent of mouth breathing in the subject. Oxygen saturation sampling is also measured by different types of oximeters using different methods of sampling, and other probes which measure respiratory movements and EEGs may differ between labs.

Interpretation of the PSG results is another area of potential uncertainty. Manual versus automated PSG scoring in the same lab may yield different results. Intra- and inter-rater variability may be problematic, and the definition of hypopnea varies, which results in different AHI measurements.

Repeatability and reproducibility of PSG measurements are also a concern. Serial studies with the same patient in the same lab may result in differential classifications, especially in patients whose AHI scores are close to the OSA diagnostic cut-off point.

Polysomnograms on the same patient in different labs would be expected to have even more variation due to differing measurement apparatus.

Based on the limitations of the test as described, it is clear that while lab-based PSG indices provide the current reference standard, they alone are not a “gold standard” for diagnosing OSA. Even so, clinicians agree that from a pragmatic point of view, the PSG information is important in the management of patients with disturbed sleep. Interestingly, no “strength of evidence” was assessed for this test, although it is the reference standard used throughout this report.

Methods of Measurement
Diagnosing OSA by detailing obstructive episodes is done using a variety of types of monitors in either the laboratory or home setting, and are categorized as follows:

- Type I: PSG in sleep facility
- Type II: Portable recording; same information as Type I (3 sleep arousal channels and minimum of 2 respiratory information channels)
- Type III: Portable recording; minimum of 2 respiratory channels (with no channels which differentiate waking and sleeping)
- Type IV: Portable monitors that fail Type III criteria

Compared to the current diagnostic standard (PSG), the strength of evidence is low that that Type II monitors can accurately diagnosis OSA, although there is wide variation in estimating the actual AHI, with discrepancies between the monitors and PSG as wide as negative 36 to positive 36 events/hr. In one study, the difference between the two measurements was dependent on their average value, with the portable monitor over estimating laboratory-based measurements for AHI<20 events/hr, but under estimating it in more severe cases. For Type III and IV monitors, the strength of the evidence is

moderate that they can accurately predict an elevated AHI (as determined by full PSG). Type III monitors perform better than type IV monitors at AHI cut offs of 5, 10 and 15 events/hour.

Several questionnaire designs and clinical prediction models have been used to assess sleep disordered breathing. The conclusion of study authors is that there is a low strength of evidence supporting the use of the Berlin questionnaire to screen for OSA, while other questionnaires could not be evaluated due to insufficient strength of evidence (only one study evaluating each). There is a low strength of evidence supporting the usefulness of some clinical prediction modeling in OSA diagnosis.

There was insufficient evidence for the utility of phased testing (i.e., using a screening test result to determine the next test to be performed in a series), as compared to PSG.

Predictive Utility of OSA Diagnostic Tests
There was insufficient evidence to assess the utility of preoperative screening for OSA.

With regard to the relationship between AHI and long term outcomes, using AHI greater than 30 events per hour was found to be an independent predictor of all cause mortality with a high strength of evidence. A higher AHI was also associated with incident diabetes based on a low strength of evidence. The association of diabetes and OSA may be confounded by obesity which may contribute to both conditions. There was insufficient evidence to determine an association of AHI with other clinical outcomes (e.g., cardiovascular mortality and hypertension).

Overall Summary

Although PSG (type I monitor) is considered the gold standard for diagnosing sleep apnea, the strength of evidence that AHI is a strong and independent predictor of all-cause mortality is limited to AHI > 30. The association between baseline AHI and the other long-term clinical outcomes is less robust, no current established threshold level for AHI exists that indicates the need for treatment. Type II, III and IV monitors can all accurately diagnosis OSA, although there is wide variation in estimating the actual AHI for type II monitors, and type III monitors perform better than type IV monitors. Some clinical prediction models and the Berlin questionnaire have evidence of efficacy as screening tools for OSA.

[Evidence Source]

PROCEDURE

Diagnostic testing for OSA

DIAGNOSES

Obstructive sleep apnea

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
327.20	Organic sleep apnea, unspecified
327.21	Primary central sleep apnea
327.23	Obstructive sleep apnea (adult) (pediatric)
327.27	Central sleep apnea in conditions classified elsewhere
327.29	Other organic sleep apnea
478.29	Nasopharyngeal obstruction
780.5	Sleep disturbance, unspecified
780.51	Insomnia with sleep apnea, unspecified
780.53	Hypersomnia with sleep apnea, unspecified
780.54	Hypersomnia, unspecified
780.57	Unspecified sleep apnea
ICD-9 Volume 3 (Procedure Codes)	
89.17	Polysomnogram
89.1	Other sleep disorder function tests
93.90	Non-invasive mechanical ventilation (CPAP)
CPT Codes	
95800	Sleep study, unattended, simultaneous recording: heart rate, O2 sat, respiratory analysis, sleep time
95801	Sleep study, unattended, simultaneous recording: heart rate, O2 sat, respiratory analysis
95803	Actigraphy
95805	Multiple sleep latency test
95806	Sleep study, unattended, simultaneous recording: heart rate, O2 sat, respiratory airflow and effort
95807	Sleep study,simultaneous recording: ventilation, respiratory effort, ECG or heart rate, O2 sat, attended by technologist
95808	Polysomnography: sleep staging with 1-3 additional parameters, attended by technologist
95810	Polysomnography: sleep staging with 4 or moe additional parameters, attended by technologist
95811	Polysomnography: sleep staging with 4 or more additional parameters, with initiation of CPAP, attended by technologist
HCPCS Codes	
G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation
G0399	Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels

Note: Inclusion on this list does not guarantee coverage

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

HERC Coverage Guidance – Diagnosis of Sleep Apnea in Adults
Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
	1	No public comments were received for this topic.	

CG - Treatment of sleep apnea in adults

Question: How should the Coverage Guidance *Treatment of sleep apnea in adults* be applied to the Prioritized List?

Question source: Health Technology Assessment Subcommittee

Current Prioritized List Status:

Line: 210
Condition: SLEEP APNEA AND NARCOLEPSY (See Guideline Notes 1,27,36,64,65,76)
Treatment: MEDICAL AND SURGICAL TREATMENT
ICD-9: 278.03,327.20-327.21,327.23-327.29,347.00-347.01,780.51,780.53, 780.57
CPT: 21193-21235,30117,30140,30520,31600-31610,31820,31825,42140-42160,42820-42836,96150-96154,98966-98969,99051,99060,99070, 99078,99201-99360,99366,99374,99375,99379-99412,99429-99444, 99468-99480,99605-99607
HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,S0270-S0274

GUIDELINE NOTE 27, SLEEP APNEA

Line 210

Surgery for sleep apnea for adults is only covered after documented failure of both CPAP and an oral appliance.

Current Code Placement

Code	Code Description	Current Placement on List	Recommended changes
21198	Osteotomy, mandible	210 SLEEP APNEA AND NARCOLEPSY 646 ANOMALIES OF RELATIONSHIP OF JAW TO CRANIAL BASE, MAJOR ANOMALIES OF JAW SIZE, OTHER SPECIFIED AND UNSPECIFIED DENTOFACIAL ANOMALIES	None

21199	Osteotomy, mandible, with genioglossus advancement	210	None
21206	Osteotomy, maxilla	210,646	None
21685	Hyoid myotomy and suspension	Excluded File	None
24145	Uvulopalatopharyngoplasty	190, 271	None
31600	Tracheostomy	11,26,78,100,210,213,214, 233,236,248,268,278 and 6 other lines.	None
41512	Tongue base suspension, permanent suture technique	171 and Excluded File	Exclude File (addressed in Straightforward issues document
41530	Radiofrequency reduction of the tongue base	Excluded File	None
42299	Unlisted procedure, palate, uvula (use for laser assisted uvulopalatoplasty (LAUP), somnoplasty, palatal implants)	Ancillary File	None
A4604	Tubing with integrated heating element for use with positive airway pressure device	Ancillary File	None
A7033	Pillow for use on nasal cannula type interface, replacement only, pair	Ancillary File	None
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap	Ancillary File	None
A7035	Headgear used with positive airway pressure device	Ancillary File	None
A7036	Chinstrap used with positive airway pressure device	Ancillary File	None
A7037	Tubing used with positive airway pressure device	Ancillary File	None
A7038	Filter, disposable, used with positive airway pressure device	Ancillary File	None
A7039	Filter, nondisposable, used with positive airway pressure device	Ancillary File	None
A7524	Tracheostoma stent/stud/button, each	Ancillary File	None
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)	Ancillary File	None
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)	Ancillary File	None
E0472	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)	Ancillary File	None
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or	Ancillary File	None

	nonadjustable, prefabricated, includes fitting and adjustment		
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment	Ancillary File	None
E0601	Continuous airway pressure (CPAP) device	Ancillary File	None

Coverage Guidance:

Coverage of treatment for Obstructive Sleep Apnea (OSA) in adults should be limited, as follows:
CPAP should be covered initially when all of the following conditions are met:

- 12 week 'trial' period to determine benefit. This period is covered if apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour, or if between 5 and 14 events with additional symptoms including excessive daytime sleepiness (Epworth Sleepiness Scale score > 10), or documented hypertension, ischemic heart disease, or history of stroke;

- Providers must provide education to patients and caregivers prior to use of CPAP machine to ensure proper use; and

- Positive diagnosis through polysomnogram (PSG) or Home Sleep Test (HST).

CPAP coverage subsequent to the initial 12 weeks should be based on documented patient tolerance, compliance, and clinical benefit. Compliance (adherence to therapy) is defined as use of CPAP for at least four hours per night on 70% of the nights during a consecutive 30 day period.

Coverage of mandibular advancement devices (oral appliances) should be provided.

Intensive weight loss programs (if provided in the benefit package) should be covered for patients with obesity and obstructive sleep apnea.

Surgical options may be covered for treatment of OSA when a diagnosis has been made, CPAP or other non-invasive treatments are not effective or not tolerated, and patients have been informed of the benefits and risks of surgery.

CG - Treatment of sleep apnea in adults

Summary
Greater clarification should be added to the Prioritized List guideline on the treatment of sleep apnea. Intensive weight loss is already covered on Line 8. Oral appliances are covered if the diagnosis is above the funding line. There is insufficient evidence on specific surgeries to make changes to the current prioritization decisions. The current CG language is a little unclear as to what needs to be failed (any non-invasive treatment? i.e. tongue exercises or intensive weight loss therapy) prior to covering surgery.

HERC Staff Recommendations:

1. Modify Guideline Note 27, Sleep Apnea, as follows:

   GUIDELINE NOTE 27, SLEEP APNEA

   Line 210

   Continuous Positive Airway Pressure devices (CPAP) should be covered initially when all of the following conditions are met:

   - 12 week 'trial' period to determine benefit. This period is covered if apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour, or if between 5 and 14 events with additional symptoms including excessive daytime sleepiness (Epworth Sleepiness Scale score > 10), or documented hypertension, ischemic heart disease, or history of stroke;

   - Providers must provide education to patients and caregivers prior to use of CPAP machine to ensure proper use; and

   - Positive diagnosis through polysomnogram or Home Sleep Test

   CPAP coverage subsequent to the initial 12 weeks should be based on documented patient tolerance, compliance, and clinical benefit. Compliance (adherence to therapy) is defined as use of CPAP for at least four hours per night on 70% of the nights during a consecutive 30 day period.

   Surgery for sleep apnea for adults is only covered after a diagnosis of sleep apnea has been made, there is documented failure or intolerance *of both CPAP and an oral appliance*, and patients have been informed of the benefits and risks of surgery.

2. Consider making the following recommendation to HERC as they review HTAS Coverage Guidance:

HERC COVERAGE GUIDANCE

Coverage of treatment for Obstructive Sleep Apnea (OSA) in adults should be limited, as follows:

CPAP should be covered initially when all of the following conditions are met:

- 12 week 'trial' period to determine benefit. This period is covered if apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour, or if between 5 and 14 events with additional symptoms including excessive daytime sleepiness (Epworth Sleepiness Scale score > 10), or documented hypertension, ischemic heart disease, or history of stroke;

- Providers must provide education to patients and caregivers prior to use of CPAP machine to ensure proper use; and

- Positive diagnosis through polysomnogram (PSG) or Home Sleep Test (HST).

CPAP coverage subsequent to the initial 12 weeks should be based on documented patient tolerance, compliance, and clinical benefit. Compliance (adherence to therapy) is defined as use of CPAP for at least four hours per night on 70% of the nights during a consecutive 30 day period.

Coverage of mandibular advancement devices (oral appliances) should be provided. Intensive weight loss programs (if provided in the benefit package) should be covered for patients with obesity and obstructive sleep apnea.

Surgical options may be covered for treatment of OSA when a diagnosis has been made, CPAP and at least one ~~or~~ other non-invasive treatment~~s~~ are not effective or not tolerated, and patients have been informed of the benefits and risks of surgery.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: TREATMENT OF SLEEP APNEA IN ADULTS

DRAFT AS REFERRED BY HTAS TO HERC 11/26/2012

HERC COVERAGE GUIDANCE

Coverage of treatment for Obstructive Sleep Apnea (OSA) in adults should be limited, as follows:

CPAP should be covered initially when all of the following conditions are met:

- 12 week 'trial' period to determine benefit. This period is covered if apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour, or if between 5 and 14 events with additional symptoms including excessive daytime sleepiness (Epworth Sleepiness Scale score > 10), or documented hypertension, ischemic heart disease, or history of stroke;
- Providers must provide education to patients and caregivers prior to use of CPAP machine to ensure proper use; and
- Positive diagnosis through polysomnogram (PSG) or Home Sleep Test (HST).

CPAP coverage subsequent to the initial 12 weeks should be based on documented patient tolerance, compliance, and clinical benefit. Compliance (adherence to therapy) is defined as use of CPAP for at least four hours per night on 70% of the nights during a consecutive 30 day period.

Coverage of mandibular advancement devices (oral appliances) should be provided.

Intensive weight loss programs (if provided in the benefit package) should be covered for patients with obesity and obstructive sleep apnea.

Surgical options may be covered for treatment of OSA when a diagnosis has been made, CPAP or other non-invasive treatments are not effective or not tolerated, and patients have been informed of the benefits and risks of surgery.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCE

Gleitsmann, K., Kriz, H., Thielke, A., Bunker, K., Ryan, K., Lorish, K., & King, V. (2012). *Sleep apnea diagnosis and treatment in adults.* Produced for the Washington HTA Program. Olympia, WA: Center for Evidence-based Policy, Oregon Health and Science University for the Washington Health Technology Assessment Program. Retrieved September 13, 2012, from http://www.hta.hca.wa.gov/documents/sleep_apnea_final_report.pdf

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Obstructive sleep apnea (OSA) refers to sleep-disordered breathing due to the recurrent collapse of pharyngeal tissues resulting in snoring, fitful sleep, and daytime somnolence. These episodes are characterized by either reduced airflow (hypopnea), or a complete obstruction (apnea), with a subsequent drop in oxygen saturation, interfering with gas exchange. Obstructive sleep apnea is a cause of significant morbidity and mortality and is associated with hypertension, neuropsychological impairment, motor vehicle accidents, stroke, cardiovascular disease, diabetes, and decreased quality of life. The prevalence of OSA is 2 to 7% in the general adult population. Prevalence increases steadily with age, to approximately 20% among people older than age 60. Risk factors for OSA include male gender, age, obesity, airway characteristics, familial/genetic predisposition, smoking, and alcohol consumption. The majority of

patients with OSA are asymptomatic, unaware of their sleep disordered breathing and associated health risks.

There have been various modalities developed to treat OSA, most attempting to reduce the airway obstructive component. Continuous positive airway pressure (CPAP) is the first-line therapy for OSA and opens the airway with compressed air. However, the CPAP machinery required is poorly tolerated and compliance is a major concern. Various oral appliances, which attempt to splint open the airway, have been used as an alternative to CPAP. Surgical procedures, including various surgeries on the oropharyngeal anatomy to alter airway mechanics, are performed to treat OSA. Bariatric surgery may be performed to reduce the volume of obstructive tissues. Other interventions that have been used to treat OSA include: weight loss regimens; smoking cessation; caffeine and alcohol avoidance; positional therapy; oropharyngeal physical therapy to strengthen the musculature and reduce obstruction; arrhythmia treatment for nocturnal bradycardia; complementary and alternative medicine (e.g., acupuncture), and a variety of pharmacologic agents.

Evidence Review

Continuous Positive Airway Pressure

A moderate strength of evidence was found for the effectiveness of treatment of OSA with CPAP. However, there was insufficient evidence to determine which patients CPAP might benefit the most. The reviewed studies report sufficient evidence supporting large improvements in sleep measures with CPAP compared with control (e.g., reducing apnea hypopnea index (AHI), improving symptoms as measured by the Epworth Sleepiness Scale[1], reducing arousal index, and raising the minimum oxygen saturation). Weak evidence demonstrated no consistent benefit in improving quality of life, neurocognitive measures or other intermediate outcomes. Despite no or weak evidence for an effect of CPAP on clinical outcomes, given the large magnitude of effect on the intermediate outcomes of AHI and Epworth Sleepiness Scale, the strength of evidence that CPAP is an effective treatment to alleviate sleep apnea signs and symptoms was rated moderate. However, the link between AHI reduction and long term clinical outcomes is not directly proven. There was insufficient evidence regarding most comparisons of various different CPAP devices, including nasal vs. oral, bilevel vs. fixed, flexible bilevel vs. fixed and humidified vs. non-humidified. However, there was a low strength of evidence that C-Flex (a proprietary CPAP technology that reduces the pressure slightly at the beginning of exhalation) is not significantly different than fixed CPAP in compliance or other outcomes, and a moderate strength of evidence that autoCPAP and fixed CPAP result in similar compliance and treatment effects.

Other Treatments for Obstructive Sleep Apnea

Mandibular advancement devices (oral appliances) had moderate strength of evidence supporting their use as an effective treatment for OSA. However, as with CPAP, there was insufficient evidence to indicate which patients might benefit from their use. There

[1] A self-administered questionnaire that measures sleep propensity, total score ranges 0-24. Reference range is defined as ≤ 10, with 1 point change considered clinically significant. Sensitivity 49% and specificity 80% for detecting OSA using an AHI cutoff of 5 events/hour, based on one high quality study.

was moderate evidence that the use of CPAP is superior to mandibular advancement devices with regard to improved sleep study measures, but weak evidence that there is minimal difference between the two for improving compliance, treatment response, quality of life or neurocognitive measures. There was insufficient evidence to compare the different oral devices, other than mandibular advancement devices.

Six surgical interventions for the treatment of OSA were reviewed (uvulopalatopharyngoplasty (UPPP), laser-assisted uvulopalatoplasty (LAUP), radiofrequency ablation (RFA), and combinations of pharyngoplasty, tonsillectomy, adenoidectomy, genioglossal advancement septoplasty, radiofrequency ablation of the inferior nasal turbinates, or combination nasal surgery) compared to sham, conservative therapy or no treatment. No surgical interventions were compared to each other. Overall there was insufficient evidence with which to evaluate their efficacy. When each modality was compared to CPAP, the evidence was insufficient to determine their relative merits. No evidence that met inclusion criteria was identified for any other surgical procedures.

Of the other treatments for OSA that were considered, only intensive weight loss programs were an effective treatment in obese patients with OSA with a low strength of evidence. The remainder of the other management modalities (e.g., atrial overdrive pacing, medications, palatal implants, oropharyngeal exercises, tongue-retaining devices with positional alarms either in isolation or in combination, bariatric surgery, acupuncture, and auricular plaster) had insufficient evidence to determine the effects of using them for treatment of OSA.

Compliance with Treatment

Compliance in OSA patients prescribed nonsurgical treatments had moderate strength of evidence that compliance was greater with CPAP use with more severe OSA and insufficient evidence regarding potential predictors of mandibular advancement devices compliance.

The strength of evidence is low for indentifying any specific intervention which may improve CPAP compliance. No intervention type (e.g., education, telemonitoring) was more promising than others.

Overall Summary

CPAP is effective for improving sleep measures (e.g., reducing AHI, improving symptoms as measured by the Epworth Sleepiness Scale, reducing arousal index, and raising the minimum oxygen saturation), but there is no evidence of consistent benefit in improving quality of life, neurocognitive measures or other intermediate outcomes. AutoCPAP and fixed CPAP result in similar compliance and treatment effects. Mandibular advancement devices are effective treatment for OSA, although CPAP is superior to mandibular advancement devices with regard to improved sleep study measures. The evidence is insufficient to evaluate the efficacy of all surgical procedures and other treatments except intensive weight loss for obese patients with OSA.

[Evidence Source]

PROCEDURE

Continuous positive airway pressure
Uvulopalatopharyngoplasty
Mandibular maxillary osteotomy
Tracheostomy

DIAGNOSES

Obstructive sleep apnea

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
327.20	Organic sleep apnea, unspecified
327.21	Primary central sleep apnea
327.23	Obstructive sleep apnea (adult) (pediatric)
327.27	Central sleep apnea in conditions classified elsewhere
327.29	Other organic sleep apnea
780.5	Sleep disturbance, unspecified
780.51	Insomnia with sleep apnea, unspecified
780.53	Hypersomnia with sleep apnea, unspecified
780.54	Hypersomnia, unspecified
780.57	Unspecified sleep apnea
ICD-9 Volume 3 (Procedure Codes)	
21.31	Nasal surgery (remove polyps)
21.88	Other septoplasty
27.64	Insertion of palatal implant
27.69	Uvulopalatopharyngoplasty
28.2	Tonsillectomy
28.3	Tonsillectomy/adenoidectomy
28.6	Adenoidectomy
31.29	Tracheostomy
93.9	CPAP
CPT Codes	
21198	Osteotomy, mandible
21199	Osteotomy, mandible, with genioglossus advancement
21206	Osteotomy, maxilla
21685	Hyoid myotomy and suspension
24145	Uvulopalatopharyngoplasty
31600	Tracheostomy
41512	Tongue base suspension, permanent suture technique
41530	Radiofrequency reduction of the tongue base
42299	Unlisted procedure, palate, uvula (use for laser assisted uvulopalatoplasty (LAUP), somnoplasty, palatal implants)
HCPCS Codes	

CODES	DESCRIPTION
A4604	Tubing with integrated heating element for use with positive airway pressure device
A7033	Pillow for use on nasal cannula type interface, replacement only, pair
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap
A7035	Headgear used with positive airway pressure device
A7036	Chinstrap used with positive airway pressure device
A7037	Tubing used with positive airway pressure device
A7038	Filter, disposable, used with positive airway pressure device
A7039	Filter, nondisposable, used with positive airway pressure device
A7524	Tracheostoma stent/stud/button, each
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0472	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment
E0601	Continuous airway pressure (CPAP) device

Note: Inclusion on this list does not guarantee coverage

HERC Coverage Guidance – Treatment of Sleep Apnea in Adults
Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
Medical Director, Health Plan Portland, OR	1	Regarding the Coverage Guidance, I have several suggestions for consideration. First would be to enhance the statement regarding excessive daytime sleepiness to require an objective evaluation of daytime sleepiness, presumably the Epworth Sleepiness Scale. This would avoid the subjectivity involved in any statement on the part of provider or DME supplier claiming member has "excessive sleepiness", without requirement of at least a standardized assessment. Likewise, "impaired cognition" is problematic in its subjectivity, although probably not wise to try and establish a standardized requirement for that condition, as it would likely lead to neuropsych testing requests, which would be of limited value in many cases (particularly if no baseline exists, as would be the case in almost every situation).	Thank you for your comment. Guidance changed to incorporate ESS into coverage guidance box. Eight trials evaluated the effect of CPAP on neurocognitive or psychological tests, all found significant benefit from CPAP. Reference to impaired cognition has been deleted from the guidance box.
	2	It might be of value to consider whether provider needs to test for alcohol use, as recommendations for abstinence from alcohol is a standard recommendation whether or not a patient is using CPAP.	Evidence source does not address this, except to list avoidance of alcohol as the conservative management arm compared to surgery.
	3	It might also be of value to specify that the provider education should cover avoidance of alcohol, avoidance of CNS-affecting medications, and the contribution of obesity to OSA, when applicable. It could even be required to document (by requesting provider) that a review of medications has been performed, focusing on current use of contraindicated medications, and avoidance of them in the future.	Evidence source does not address this, except to list weight loss, positional therapy, and avoidance of alcohol and sedatives as the conservative management arm compared to surgery. Regarding obesity, three trials of weight loss interventions (primarily diets) found a significant improvement in AHI, ESS and O2 saturation. Regarding provider education, 9 studies evaluated extra support or education to improve compliance with CPAP, however results were inconsistent. Counseling regarding weight loss has been added to the guidance box.
	4	I also believe the literature suggests that compliance with CPAP can be predicted in most cases by usage in the first few weeks, if not sooner. Is there need to have the trial period be 12 weeks-that would seem to be excessive, and given the likely high rate of non-compliance, is a 3 month trial necessary? It seems not, and a significant cost to the system. A shorter trial period might also promote the DME supplier to ensure member awareness of compliance requirements. I would propose a two-stage trial period-the first of 4-6 weeks to establish compliance, and if that first criteria is met, a second criteria at 12-16 weeks to evaluate for effectiveness.	The evidence source identified 5 studies that evaluated predictors of compliance, which included higher AHI, higher ESS score, younger age, snoring, lower CPAP pressure, higher BMI, higher mean oxygen saturation. One of those trials evaluated compliance at 4 weeks and found the only significant predictor to be high baseline AHI. There was a small (3%) decrease in the number of patients compliant with CPAP use between 4 weeks and 12 weeks. No other trials evaluated compliance or predictors of compliance at 4-6 weeks.

HERC Coverage Guidance – Treatment of Sleep Apnea in Adults
Disposition of Public Comments

Stakeholder	#	Comment	Disposition
	5	It also might be helpful to objectify "effectiveness" or clinical benefit if possible. Thank you for your consideration.	Effectiveness is explained in the text, as follows: "sufficient evidence supporting large improvements in sleep measures with CPAP compared with control (e.g., reducing apnea hypopnea index (AHI), improving symptoms as measured by the Epworth Sleepiness Scale, reducing arousal index, and raising the minimum oxygen saturation). Weak evidence demonstrated no consistent benefit in improving quality of life, neurocognitive measures or other intermediate outcomes."
Industry Location Unknown	6	In response to the draft coverage guidance: Treatment of sleep apnea in adults, I guess my first response would be; is this the full policy? It appears that it may be a summary of medical necessity but does not have guidelines which currently exist in this policy such as when to bill for the sale of the item. For example the current policy has has "a three month trial (rental) period for CPAP is required prior to purchase", the draft does not mention a change in therapy, existing policy states "If a CPAP device was used more than three months and the client is switched to a RAD, then the clinical re-evaluation would occur between the 61st and 91st day following initiation of the RAD".	This document provides general guidance only. Specific implementation of the policy is left to individual payers.
	7	I guess my overall confusion is what is the reasoning for the "draft" is it just in terms of medical appropriateness and nothing further or is the "draft" intended to replace the current rule? If it is intended to replace the current rule it appears to be missing many factors that are vital to providers. Thank you.	Yes, the intent is to address general medical appropriateness, not to replace the current DMAP rule.

CG - MRI for Breast Cancer Diagnosis

Question: How should the Coverage Guidance *MRI for Breast Cancer Diagnosis* be applied to the Prioritized List?

Question source: Health Technology Assessment Subcommittee

Coverage Guidance:
In women with recently diagnosed breast cancer, preoperative or contralateral MRI of the breast should not be a covered service.

Current Prioritized List status:

Code	Description	List Placement
77058	MRI breast, with or without contrast, unilateral	Diagnostic File
77059	MRI breast, with or without contrast, bilateral	Diagnostic File
C8903	Magnetic resonance imaging with contrast, breast; unilateral	Ancillary File
C8904	Magnetic resonance imaging without contrast, breast; unilateral	Ancillary File
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral	Ancillary File
C8906	Magnetic resonance imaging with contrast, breast; bilateral	Ancillary File
C8907	Magnetic resonance imaging without contrast, breast; bilateral	Ancillary File
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral	Ancillary File

HERC Staff Recommendations:

1. Adopt new Diagnostic Guideline

DIAGNOSTIC GUIDELINE XX
In women with recently diagnosed breast cancer, preoperative or contralateral MRI of the breast is not a covered service.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: MRI FOR BREAST CANCER DIAGNOSIS

DRAFT AS REFERRED BY HTAS TO HERC 11/26/12

HERC COVERAGE GUIDANCE

In women with recently diagnosed breast cancer, preoperative or contralateral MRI of the breast should not be a covered service.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. In addition to an evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Heath Technology Assessment Subcommittee, coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Healthcare Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program.

EVIDENCE SOURCE

Washington State Health Care Authority Health Technology Assessment Program. (2010). *HTA Report: Breast MRI in diagnosis and treatment of cancer in women at high risk*. Olympia, WA: Health Technology Assessment Program. Retrieved May 7, 2012, from http://www.hta.hca.wa.gov/documents/breast_mri_072310_final.pdf

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

In 2009, an estimated 192,370 cases and 40,170 deaths occurred in women with breast cancer. In 2002, the United States Preventive Services Task Force found adequate evidence of film mammography's sensitivity and specificity and evidence of mammography's effectiveness in decreasing breast cancer mortality in women at average risk and concluded that film mammography was the standard for detecting breast cancer in women at average risk of developing breast cancer. In women recently diagnosed with breast cancer, MRI has been used to evaluate the contralateral breast, and has also been used to assist with treatment planning prior to definitive treatment. Whether these uses of breast MRI improve patient outcomes is not clear, and is the focus of this report.

Evidence Review

Detecting Contralateral Breast Cancer in Women Recently Diagnosed
MRI detects contralateral breast lesions in a substantial proportion of women with breast cancer, but does not reliably distinguish benign from malignant findings. This evidence review identified the following results:

- Detection of suspicious findings (true positives plus false positives): 9.3% (95% CI, 5.8% to 14.7%)
- Incremental cancer detection rate (ICDR): 4.1% (95% CI, 2.7% to 6.0%)
- PPV, 47.9% (95% CI, 31.8% to 64.6%)
- True positive: false positive ratio, 0.92 (95% CI, 0.47 to 1.82).

Some women will undergo treatment changes based on false positive tests, with one study reporting that 6.9% of women with changes in treatment based on MRI were found to have benign lesions. There were no RCTs which assessed the effect of adding MRI to conventional breast cancer screening on mortality rates.

Changes in Treatment in Women with Recently Diagnosed Breast Cancer
Preoperative MRI testing in women with recently diagnosed breast cancer will change treatment plans for some women (15.7%). Conversion of wide local excision to more extensive surgery will occur in up to 11.3% of women, and conversion from wide excision to mastectomy will occur in up to 8.1% of women. In women with breast cancer with dense breast tissue, microcalcifications suspicious for carcinoma in situ or discordance between mammography and ultrasound, MRI may add clinical information which may alter treatment plans (44.3% of the time in one retrospective observational study).

Changes in Treatment – Incomplete Excision
Adding MRI will change treatment plans and result in more extensive surgery for some women, but may not change incomplete excision rates or breast cancer recurrence

rates. The evidence is insufficient to determine whether MRI affects the rate of incomplete cancer excision because it is conflicting. One study found no difference between groups while another found an 18% decrease in re-excision rates in women who underwent MRI preoperatively. The study reporting of no difference between groups may have been underpowered to find a difference if one existed. The evidence is insufficient to determine whether changes in treatment plans based on the results of preoperative MRI testing are beneficial.

Changes in Treatment – Recurrence Rates

The evidence regarding the effect of preoperative MRI testing in women with early invasive breast cancer on recurrence rates is inconclusive. One retrospective observational study reported a 5.6% reduction in recurrence rates in patients receiving preoperative MRI before breast conservation surgery. Another larger observational study found that MRI was not associated with a lower recurrence rate or 8-year rate of local failure.

Safety

Gadolinium-based MRI contrast agents appear to be safe. There is no evidence of adverse events associated with MRI radiation exposure. We found no evidence that breast implants increase the risk of developing breast cancer. The evidence is insufficient to conclude that false-positive breast cancer screening or testing results lead to clinically meaningful negative psychological outcomes.

Technical and Provider Issues in MRI Testing

The evidence is insufficient to establish technical MRI specifications or provider qualifications.

[Evidence Source]

Overall Summary

MRI of the breast identifies contralateral breast lesions in women who have been recently diagnosed with breast cancer and may result in a change in treatment plans, but some women will undergo those changes based on false positive tests, and whether those changes are beneficial is unknown. Preoperative MRI testing in women with recently diagnosed breast cancer may change treatment plans, but there is no clear evidence that it changes incomplete excision rates or breast cancer recurrence rates. There is no evidence of a benefit on mortality with contralateral or preoperative MRI of the breast.

PROCEDURE

MRI of the Breast

DIAGNOSES

Breast cancer

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Codes	
V10.3	Personal history of malignant neoplasm, breast
V16.3	Family history of malignant neoplasm, breast
V76.10	Special screening for malignant neoplasms, breast, unspecified
V76.19	Special screening for malignant neoplasms, breast, other screening breast examination
V84.01	Genetic susceptibility to malignant neoplasm of breast
174.0-9	Malignant neoplasm of female breast
233.0	Carcinoma in situ of breast
ICD-9 Volume 3 (procedure codes)	
None	
CPT Codes	
77058	MRI breast, with or without contrast, unilateral
77059	MRI breast, with or without contrast, bilateral
HCPCS Codes	
C8903	Magnetic resonance imaging with contrast, breast; unilateral
C8904	Magnetic resonance imaging without contrast, breast; unilateral
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
C8906	Magnetic resonance imaging with contrast, breast; bilateral
C8907	Magnetic resonance imaging without contrast, breast; bilateral
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral

HERC Coverage Guidance – MRI for Breast Cancer Diagnosis
Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
	1	No public comments were received for this topic.	

COVERAGE GUIDANCE
Vertebroplasty, kyphoplasty, and sacroplasty

Question: How should the Coverage Guidance - *Vertebroplasty, kyphoplasty, and sacroplasty* be applied to the Prioritized List?

Question source: Health Technology Assessment Subcommittee

Coverage Guidance box:

Vertebroplasty and kyphoplasty should not be covered for routine osteoporotic compression fractures.

An osteoporotic compression fracture is not "routine" if:

1. The patient is hospitalized under inpatient status due to pain that is primarily related to a well-documented acute fracture, and
2. The severity of the pain prevents unassisted ambulation, and
3. The pain is not adequately controlled with oral or transcutaneous medication.

The patient must have failed an appropriate trial of conservative management.

Sacroplasty should not be covered.

Current Prioritized List Status:

Code	Description	Current Prioritized List Placement
22520	Percutaneous vertebroplasty, 1 vertebral body, unilateral or bilateral injection; thoracic	DMAP Excluded File
22521	Lumbar	DMAP Excluded File
+22522	each additional thoracic or lumbar vertebral body	DMAP Excluded File
22523	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); thoracic	DMAP Excluded File
22524	Lumbar	DMAP Excluded File
+22525	each additional thoracic or lumbar vertebral body	DMAP Excluded File
22899	Unlisted procedure, spine	DMAP Ancillary File
72291	Radiological supervision and interpretation, percutaneous vertebroplasty, vertebral	507 CLOSED DISLOCATIONS/FRACTURES OF

	augmentation, or sacral augmentation (sacroplasty), including cavity creation, per vertebral body or sacrum; under fluoroscopic guidance	NON-CERVICAL VERTEBRAL COLUMN WITHOUT SPINAL CORD INJURY
72292	Radiological supervision and interpretation, percutaneous vertebroplasty, vertebral augmentation, or sacral augmentation (sacroplasty), including cavity creation, per vertebral body or sacrum; under CT guidance	507
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles	Not on List
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injection(s), including the use of a balloon or mechanical device, when used, 2 or more needles	Not on List
HCPCS Codes		
S2360	Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; cervical	507
S2361	Each additional cervical vertebral body	507

Line: 158
Condition: CERVICAL VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR CLOSED; OTHER VERTEBRAL DISLOCATIONS/FRACTURES, OPEN; SPINAL CORD INJURIES WITH OR WITHOUT EVIDENCE OF VERTEBRAL INJURY (See Guideline Notes 1,6,64,65,76)
Treatment: MEDICAL AND SURGICAL TREATMENT
ICD-9: 733.13,805.00-805.18,805.3,805.5,805.7,805.9,806.00-806.9,839.00-839.18,839.30-839.31,839.50-839.59, 839.71-839.79,839.9,952.00-952.9,V54.01,V54.09,V54.17,V57.1,V57.21-V57.3,V57.81-V57.89
CPT: 11010-11012,20660,20661,20665,20690-20694,20900,20930-20938,22100-22116,22305-22505,22532-22819, 22840-22855,27202-27216,29015,29025,29040,29710-29720,63001-63173,63295,96150-96154,97001-97004, 97012,97022,97110-97124,97140-97530,97535,97542,97760-97762,98966-98969,99051,99060,99070,99078, 99201-99360,99366,99374,99375,99379-99412,99429-99444,99468-99480,99605-99607
HCPCS: G0157-G0161,G0396,G0397,G0406-G0408,G0425-G0427,S0270-S0274

Line: 507
Condition: CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT SPINAL CORD INJURY (See Guideline Notes 6,64,65,76)
Treatment: MEDICAL AND SURGICAL TREATMENT
ICD-9: 733.13,805.2,805.4,805.6,805.8,809.0,839.40,839.42-839.49,905.1,V57.1,V57.21-V57.3,V57.81-V57.89
CPT: 20930-20938,22305,22310,22325-22328,22526-22819,22840-22855,27216,27218,29035-29046,29700,29710, 29720,63001-63011,72291,72292,97001-97004,97012,97022,97110-97124,97140-97530,97535,97542,97760-97762,98966-98969,99051,99060,99070,99078,99201-99360,99366,99374,99375,99379-99412,99429-99444, 99468-99480,99605-99607
HCPCS: G0157-G0161,G0396,G0397,G0406-G0408,G0425-G0427,S0270-S0274,S2360,S2361

HERC Staff Assessment

Currently, some of the codes for vertebroplasty, kyphoplasty, and sacroplasty are on the Prioritized List, others are Excluded. Additionally, some of the cervical hcpcs codes are on a non-cervical line. In reviewing the supporting literature, none of the studies specifically evaluated cervical fractures and many excluded them. Medicare only allows for vertebroplasty for thoracolumbar fractures (T5-L5). Compression fractures of the neck seem largely due to trauma, rather than osteoporotic fractures. Treatment of cervical fractures with vertebroplasty or kyphoplasty is not supported by the literature, and codes should not be paired in the higher prioritized region of the List (e.g. Line 158).

HERC Staff Recommendations:

1) **Remove** S2360 and S2361(cervical vertebroplasty codes) from the List and recommend placement in the *DMAP Excluded File*
2) **Add** CPT codes 22520-22525 (thoracolumbar vertebroplasty codes) to line 507 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT SPINAL CORD INJURY
3) **Add a guideline**

GUIDELINE NOTE XXX
LINE 507

Vertebroplasty and kyphoplasty are not included on this line (or any other line) for the treatment of routine osteoporotic compression fractures.

Vertebroplasty and kyphoplasty are only included on this line for the treatment of vertebral osteoporotic compression fractures when they are considered non-routine and meet all of the following conditions:

1. The patient is hospitalized under inpatient status due to pain that is primarily related to a well-documented acute fracture, and
2. The severity of the pain prevents unassisted ambulation, and
3. The pain is not adequately controlled with oral or transcutaneous medication, and
4. The patient must have failed an appropriate trial of conservative management.

Sacroplasty is not included on these or any lines of the Prioritized List for coverage consideration.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

DRAFT COVERAGE GUIDANCE: VERTEBROPLASTY, KYPHOPLASTY, SACROPLASTY

REFERRED BY HTAS TO HERC 11/26/2012

HERC COVERAGE GUIDANCE

Vertebroplasty and kyphoplasty should not be covered for routine osteoporotic compression fractures.

An osteoporotic compression fracture is not "routine" if:

1. The patient is hospitalized under inpatient status due to pain that is primarily related to a well-documented acute fracture, and
2. The severity of the pain prevents unassisted ambulation, and
3. The pain is not adequately controlled with oral or transcutaneous medication.

The patient must have failed an appropriate trial of conservative management.

Sacroplasty should not be covered.

Note: This coverage guidance does not address vertebral fractures related to malignancy.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCE

Washington State Health Care Authority Health Technology Assessment Program. (2010). *Vertebroplasty, kyphoplasty and sacroplasty: Health technology assessment.* Olympia, WA: Health Technology Assessment Program. Retrieved March 20, 2012, from http://www.hta.hca.wa.gov/documents/vks_final_report.pdf

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

Clinical Background

Vertebral compression fractures and sacral insufficiency fractures often result in considerable pain, loss of function, and decreased quality of life. Patients with osteopenic vertebral or sacral fractures are at greater risk of morbidity and mortality, yet operative intervention (e.g., fusion with instrumentation) may be problematic in this elderly population making less invasive methods more attractive.

Vertebroplasty, kyphoplasty and sacroplasty (collectively, percutaneous vertebral and sacral surgery) are surgical procedures used to treat spinal pain believed to be caused by fractures in the vertebra or sacrum. These are all cementoplasty techniques that are thought to relieve pain by stabilizing the fractured bone(s), but the mechanism of pain relief is not clear. Osteoporosis, vertebral metastasis and multiple myeloma are the most frequently reported indications for these procedures.

Vertebroplasty involves injection of bone cement into a partially collapsed vertebral body under computed tomography (CT) or fluoroscopic guidance. Kyphoplasty is a modification of vertebroplasty that expands the partially collapsed vertebral body with an inflatable balloon before the injection of bone cement. Sacroplasty is an extension of vertebroplasty, involving the injection of bone cement into the sacrum to repair sacral insufficiency fractures.

These surgical procedures are less invasive than other spinal surgical procedures, but more invasive than conservative medical therapy. Although a number of non-randomized studies have reported improvements in pain and functioning following these procedures, significant questions remain about their safety, efficacy and effectiveness, and cost effectiveness.

Evidence Review

Efficacy/Effectiveness

Vertebroplasty vs. sham surgery or conservative medical therapy

In two RCTs, vertebroplasty was no more effective than sham surgery in reducing pain or improving function or quality of life at one month and three months. In a large RCT comparing vertebroplasty with conservative medical therapy, vertebroplasty was more effective than conservative treatment in reducing self-reported pain intensity for follow-

up points of up to one year. In two small RCTs, vertebroplasty and conservative medical therapy patients showed comparable improvement in pain, with inconsistent findings for functional outcomes. In four cohort studies (two prospective and two retrospective), vertebroplasty was more effective than conservative medical therapy in reducing pain up to six months, but pain levels were comparable for the two groups after one year. For a very limited set of functional outcomes, vertebroplasty led to earlier improvements than conservative medical therapy, followed by equivalent levels of functioning after six months to a year.

Kyphoplasty (KP) vs. conservative medical therapy

In one RCT, kyphoplasty was more effective than conservative medical therapy in reducing pain intensity for follow-up points up to one year. Pain was reduced more rapidly in kyphoplasty patients, and although the group differences were diminished by 12 months, they remained statistically significant. Kyphoplasty was also more effective than conservative medical therapy in improving functional outcomes over one year; again, group differences were diminished at 12 months but remained statistically significant. In two cohort studies (one prospective and one retrospective), kyphoplasty reduced pain more than conservative medical therapy for periods up to three years, and kyphoplasty improved a limited set of functional outcomes more than conservative medical therapy.

Vertebroplasty vs. kyphoplasty

One poor-quality RCT found that back pain scores improved equally for vertebroplasty and kyphoplasty patients over six months. Evidence from 12 cohort studies (six prospective and six retrospective) demonstrated that vertebroplasty and kyphoplasty led to comparable pain reduction at follow-up periods up to two years in 8 of 10 studies, and that vertebroplasty and kyphoplasty demonstrated comparable improvements at follow-up times up to two years in four of five studies.

Sacroplasty

No comparative studies were identified; case series suggest improvement in pain following sacroplasty.

Safety

Vertebroplasty and kyphoplasty

New fractures: In comparative studies, the rate of new fractures at any location following vertebroplasty, kyphoplasty, or conservative medical therapy was up to 25% at six months post-surgery, and up to 30% at 12 months, with no consistent pattern across studies in different rates for vertebroplasty, kyphoplasty, and conservative medical therapy. In cohort studies, from 22% to 66% of new fractures occurred in adjacent vertebrae, however, these rates are based on very small numbers. A systematic review concluded that the proportion of new fractures that were adjacent was higher for kyphoplasty (75%) than for vertebroplasty (52%). Systematic reviews of case series report slightly higher rates of new fractures at any location for vertebroplasty (16-21%) than for kyphoplasty (7-17%).

Cement leakage: Rates of asymptomatic cement leakage are up to 80% for vertebroplasty and 50% for kyphoplasty. Comparative studies and systematic reviews

(consisting largely of case series) suggest that cement leakage is greater in vertebroplasty than in kyphoplasty; however, symptomatic leaks are rare.

Pulmonary cement embolism (PCE): One RCT reported a PCE rate for vertebroplasty of 26%, with all cases asymptomatic. Systematic reviews of case series report pooled PCE rates from 0.1% to 1.7%, with insufficient information to compare rates for vertebroplasty and kyphoplasty.

Mortality (data from systematic reviews primarily of case series): Rates in prospective studies of 2.1% for vertebroplasty and 0.6% for retrospective studies. Overall mortality for kyphoplasty ranged from 2.3% to 3.2% in 2 different reviews. Perioperative mortality was 0.01%.

Sacroplasty
Across four case series, rate of cement leakage was 20.5%.

[Evidence Source]

Overall Summary

Vertebroplasty is no more effective than sham surgery, and comparisons to conservative medical therapy are inconsistent. Vertebroplasty appears to have similar efficacy as kyphoplasty. No trials of kyphoplasty to sham surgery have been conducted, but kyphoplasty may be more effective than conservative medical therapy early on, although differences diminish by 12 months. There are no RCTs of sacroplasty. Mortality rates for vertebroplasty and kyphoplasty range from 0.6% to 3.2%, and both are associated with high rates of cement leakage.

PROCEDURE

Vertebroplasty
Kyphoplasty
Sacroplasty

DIAGNOSES

Vertebral compression fracture
Sacral insufficiency fracture

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
733.13	Pathologic fracture of vertebrae
805.00	Closed fracture of cervical vertebra, unspecified level
805.01	Closed fracture of first cervical vertebra
805.02	Closed fracture of second cervical vertebra
805.03	Closed fracture of third cervical vertebra

CODES	DESCRIPTION
805.04	Closed fracture of fourth cervical vertebra
805.05	Closed fracture of fifth cervical vertebra
805.06	Closed fracture of sixth cervical vertebra
805.07	Closed fracture of seventh cervical vertebra
805.08	Closed fracture of multiple cervical vertebrae
805.2	Closed fracture of dorsal [thoracic] vertebra without mention of spinal cord injury
805.4	Closed fracture of lumbar vertebra without mention of spinal cord injury
805.6	Closed fracture of sacrum and coccyx without mention of spinal cord injury
805.8	Closed fracture of unspecified vertebral column without mention of spinal cord injury
ICD-9 Volume 3 (Procedure Codes)	
81.65	Percutaneous Vertebroplasty
81.66	Percutaneous Vertebral Augmentation
CPT Codes	
22520	Percutaneous vertebroplasty, 1 vertebral body, unilateral or bilateral injection; thoracic
22521	lumbar
+22522	each additional thoracic or lumbar vertebral body
22523	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); thoracic
22524	lumbar
+22525	each additional thoracic or lumbar vertebral body
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injection(s), including the use of a balloon or mechanical device, when used, 2 or more needles
72291	Radiological supervision and interpretation, percutaneous vertebroplasty, vertebral augmentation, or sacral augmentation (sacroplasty), including cavity creation, per vertebral body or sacrum; under fluoroscopic guidance
72292	Radiological supervision and interpretation, percutaneous vertebroplasty, vertebral augmentation, or sacral augmentation (sacroplasty), including cavity creation, per vertebral body or sacrum; under CT guidance
HCPCS Codes	
S2360	Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; cervical
S2361	Each additional cervical vertebral body

Note: Inclusion on this list does not guarantee coverage

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

HERC Coverage Guidance – Vertebroplasty, Kyphoplasty, Sacroplasty
Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
American Association of Orthopaedic Surgeons Washington, D.C	1	Thank you for the opportunity to comment on the draft guidance regarding vertebroplasty, kyphoplasty, and sacroplasty for routine osteoporotic compression fractures. The American Association of Orthopaedic Surgeons represents 98% of the orthopaedic surgeons practicing in the United States, 368 of who practice in Oregon. Orthopaedic surgeons are the preeminent physicians providing surgical treatment for musculoskeletal conditions and disease. I currently serve as the President of the AAOS and have practiced in Tualatin, Oregon for more than 30 years.	Thank you for taking the time to comment.
	2	The AAOS firmly supports the incorporation of evidence into clinical practice, and is actively involved in developing and promoting Evidence Based Clinical Practice Guidelines for a number of musculoskeletal conditions, including The Treatment of Symptomatic Osteoporotic Spinal Compression fractures (http://www.aaos.org/research/guidelines/SCFguideline.pdf), for which the corresponding Summary of Recommendations is attached.	Thank you for providing this reference. The HTAS appreciates the AAOS' interest in producing evidence-based practice guidelines, and is impressed by the rigor of your development process.
	3	Through the AAOS' rigorously researched evidence-based clinical practice guideline development process, the AAOS has determined that the three procedures addressed in your draft coverage guidance are distinct from each other and deserving of similarly distinct treatment in terms of coverage guidance. Recommendation 8 of the AAOS clinical practice guideline recommends "against vertebroplasty for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact" (Grade of Recommendation: A). The Oregon Draft Coverage Guidance is consistent with this recommendation.	The HTAS agrees.
	4	However, Recommendation 9 of the AAOS clinical practice guideline states that "kyphoplasty is an option for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact" (Grade of Recommendation: C). The Oregon Draft Coverage Guidance is inconsistent with this recommendation.	The AAOS guideline relied on 5 studies, 4 of which were included in the WA HTA review, while an updated publication of the fifth trial was included in the WA HTA. Two compared kyphoplasty to conservative treatment and 3 compared it to vertebroplasty. The 2 trials that used conservative treatment as the comparator found clinically important differences only at 1 week and 1 month in one trial, and "possibly clinically important improvement" in the other. Two of the 3 trials that used vertebroplasty as the comparator found no difference between groups, while the third found differences in

Stakeholder	#	Comment	Disposition
			favor of kyphoplasty only at 2 years. Because of the inconsistent results noted here, the AOSS downgraded the strength of their recommendation from moderate to weak, so that kyphoplasty could be an "option."
	5	The AAOS clinical practice guideline for The Treatment of Symptomatic Osteoporotic Spinal Compression Fractures does not address sacroplasty. The treatment of vertebral compression fractures by either kyphoplasty or vertebroplasty should be considered completely separately from sacroplasty for sacral insufficiency fractures, as these are distinct anatomical and pathologic conditions.	The HTAS appreciates this distinction but has chosen to address all three procedures in one guidance to reflect the scope of the evidence source. Although they are included in the same Coverage Guidance, each procedure is evaluated and recommendations are made separately.
	6	Given the distinctions between the three procedures and their evidence-based clinical practice guideline recommendations, the AAOS urges the HERC to consider amending its coverage guidance to be consistent with evidence-based clinical practice guidelines. This would mean amending the coverage guidance to read: "Vertebroplasty should not be covered for routine osteoporotic compression fractures. Kyphoplasty should be covered for routine osteoporotic compression fractures." Thank you for your consideration of these amendments.	The HTAS understands the rationale presented but does not believe the evidence pertaining to kyphoplasty is sufficiently strong to recommend coverage of the procedure.
Medtronic, Inc. Memphis, TN	7	We appreciate this opportunity to submit comments on the Health Technology Assessment Subcommittee's (HTAS) Draft Coverage Guidance for Vertebroplasty, Kyphoplasty and Sacroplasty. As you are aware, Medtronic's Spinal and Biologics division manufactures products that treat a variety of disorders of the spine. These products are utilized by spinal and orthopedic surgeons to treat patients with acute symptomatic vertebral compression fractures that are known to significantly impair quality of life and increase risk of death. We are very interested in ensuring that the coverage guidance for Kyphoplasty reflects the latest clinical evidence and standard of care.	Thank you for your comment and for providing the studies referred to in your comments.
	8	Thank you for the consideration of our previous comments submitted April 16, 2012. We applaud the HTAS decision to provide expanded coverage from the initial draft for balloon kyphoplasty (BKP), including coverage for all cancer indications and for non-routine osteoporotic compression fractures. We believe the clinical evidence clearly supports this determination. **Additionally, we believe that the evidence supports an even broader coverage determination and application for osteoporosis cases.** Recent evidence has emerged since the Washington Health Technology Assessment Program (WA HTAP) conducted their review that supports a broadened positive coverage determination. In addition, it is worth noting that the major commercial payers in Oregon, plus a Medicare Local Coverage Decision (LCD) for the Oregon region,	The HTAS makes its decisions based on evidence of effectiveness and harms, not on the basis of other payers' coverage policies.

Stakeholder	#	Comment	Disposition
		provide for a broader coverage of BKP. We ask the HTAS to adopt coverage guidance in keeping with the clinical indications of the LCD to expand coverage for patients with osteoporosis.	
	9	First, we submit the following as additional support of the HTAS positive coverage determination for BKP for all cancer indications. The growing body of evidence, including one randomized-controlled trial and two recent systematic reviews, demonstrates the relative superior safety and effectiveness of BKP compared to non-surgical management in the treatment of eligible vertebral compression fractures (VCFs) in patients with multiple myeloma or spinal metastases from primary tumors (Berenson 2011, Bouza 2009, Aghayev 2011). In addition, the National Institute for Health and Clinical Excellence (NICE, 2008) guidelines recommend cemental augmentation procedures for VCFs in cancer patients.	The search dates of the Bouza SR are included in the WA HTA review. The Aghayev review is narrative, not systematic. The Berenson RCT compared kyphoplasty to medical management in patients with malignancy, N=134, unblinded and funded by industry. Found significant decrease in pain in the KP group at 1 month. General NICE guidance for VP and KP due Dec 2012.
	10	Second, we appreciate and understand the HTAS evidence source as the WA HTAP, however, the Washington review was conducted in 2010 and relevant evidence has since emerged and should be considered as part of the HERC review. Discussion at the HTAS meeting on April 23, 2012 led to restrictions on coverage of osteoporosis cases partially because it was determined there were no long-term results regarding effectiveness. **However, studies are now available associating BKP with long-term effectiveness, increased life expectancy, and cost-effectiveness.** The final coverage guidance should reflect the latest clinical evidence and be expanded to include coverage for additional osteoporosis cases. The following randomized, controlled trials indicate that BKP has been shown to provide clinically and statistically greater pain relief, restoration of mobility, and quality of life than non-surgical management (Boonen 2011, Berenson 2011). Please see our previous correspondence where we included more detailed explanations of the studies; the studies are also attached for your review	See Comment #9 concerning Berenson. Boonen is an unblinded RCT, N=300, funded by industry. Found improved SF-36 scores averaged across 24 months compared to non-surgical management, as well as pain and function scores at 1,3,6 and 12 mos. 23% drop out rate. Excluded fractures associated with malignancy or acute trauma.
	11	The following recent retrospective analysis of Medicare data indicates that BKP has been associated with an increased life expectancy compared to non-surgical management (Edidin OI 2012). In another analysis of Medicare patients published this year, BKP was determined cost-effective compared with non-surgical management (Edidin CEA 2012). Both of these studies showing the advantages of BKP should be considered as part of the HERC review.	These are both retrospective database studies that use a model for estimating life expectancy, not actual data, as well as claims data to identify vertebral fractures and their treatment. Both are highly susceptible to bias.
	12	Lastly, as further support for our assertion that the coverage for BKP ought to be extended for additional osteoporosis cases, we submit the results of our review of the coverage polices of the top ten commercial carriers in Oregon (the majority of which were updated in 2011, after the WA HTAP review). Eight of the ten carriers publish their policies and all of them have positive coverage policies for BKP for osteoporosis cases. Judging from information gathered from provider bulletins, it is likely the remaining two do as well. **Additionally, the Medicare LCD is positive for all indications for BKP.**	The HTAS makes its decisions based on evidence of effectiveness and harms, not on the basis of other payers' coverage policies. Medicare LCD language confirmed. Entire

Stakeholder	#	Comment	Disposition
		Following are the indications for the Medicare LCD: For Both Percutaneous Vertebroplasty and Percutaneous Vertebral Augmentation: One indication – painful compression fracture, regardless of etiology, described below. Clearly demonstrated vertebral compression fracture, with severe pain, refractory to conservative treatment and referable specifically to that site – non-specific documentation of "lower back pain" or similar language will not support payment. … Neither Percutaneous Vertebroplasty nor Percutaneous Vertebral Augmentation is indicated for treatment of lesions of the sacrum or coccyx. NAS will not allow payment for any such treatment until and unless either becomes listed as a covered indication in FDA labeling AND literature supports and describes appropriate criteria for such use. The CPT Category III codes, 0200T and 0201T, are non-covered. See: http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=32032&ContrId=243&ver=11&ContrVer=1&CntrctrSelected=243*1&Cntrctr=243&name=Noridian+Administrative+Services%2c+LLC+(02301%2c+MAC+-+Part+A)&LCntrctr=243*1%7c244*1&bc=AgACAAIAAAAA& To reduce confusion for surgeons and patients, we encourage the HTAS to adopt a final coverage guidance for BKP in keeping with the indications provided in the LCD.	policy is lengthy and included as a separate document.
	13	In summary, we applaud the work of the HTAS thus far on the draft coverage for BKP for all cancer indications and for non-routine osteoporotic compression fractures. However, it is our belief that the recent and emerging clinical evidence supports a broader application of coverage for BKP for other osteoporosis cases. It associates BKP with long-term positive outcomes, increased life expectancy and cost-effectiveness. We hope the HTAS will choose to follow the existing commercial policies and the indications of the LCD for the state of Oregon; they are supported by the new data showing positive results and long-term effectiveness for BKP in osteoporosis cases. Thank you again for your consideration of our comments and the attached studies.	The provided studies do not substantially alter the conclusions of the WA HTA evidence report.
DePuy Spine Raynham, MA	14	DePuy Spine Inc. is grateful for the opportunity to provide Oregon's Health Evidence Review Commission (HERC) with comments on its draft non-coverage policy for vertebroplasty, kyphoplasty, and sacroplasty for treatment of routine osteoporotic vertebral compression fractures (VCFs). We encourage the HERC to take into account the body of evidence for these treatment options, as well as feedback from the full spectrum of treating physicians (e.g., internists, interventional radiologists, pain specialists, and surgeons) and patients to ensure that its coverage policy fosters appropriate access to evidence-based treatment for VCFs. Below we provide rationale for HERC's continued coverage of vertebroplasty and kyphoplasty for a	Thank you for your comment.

Stakeholder	#	Comment	Disposition
		carefully selected subset of patients with acute VCFs who fail to respond, or who are intolerant of, non-invasive management (NIM).	
	15	**Patients with debilitating symptoms despite an adequate trial of non-invasive management have few treatment options to reduce pain and hasten return to normal function after acute VCF.** Few treatment options are available for patients suffering from painful VCFs that are unresponsive to non-invasive management (e.g., bed rest, physical therapy, analgesia, and bracing). As a result, patients may endure months of severe pain, restricted mobility, poor quality of life (QoL), and/or depression.[1] Patients with VCFs are confined to bed nine times more often than those without VCFs, increasing their risk of further VCFs and suboptimal recovery.[2] The impact of VCFs on QoL has been estimated to be similar to that attributable to chronic obstructive pulmonary disease.[3]	HTAS understands the significant impact of VCFs on patients.
	16	**The two sham-controlled studies published in the NEJM fail to provide evidence about the role of vertebroplasty for a carefully selected subgroup of patients with acute VCFs.** Randomized controlled clinical trials (RCTs) that compared vertebroplasty to a simulated procedure (sham) highlight the challenges of conducting adequately powered RCTs of vertebroplasty, including barriers to recruitment and the need for careful patient selection.[4, 5] Subsequent to the publication of these studies in the New England Journal of Medicine (NEJM), position statements by national medical societies identified severe limitations that pose challenges to interpretation of these studies.[6, 7] Among these, high non-participation rates, the inclusion of patients with chronic fractures, measurement of "overall pain" rather than back pain, significant crossover from NIM, potential analgesic effect from peri-facet injection, as well as limited statistical power warrant particular concern. Further, the studies' investigators did not require clinical correlation of fracture level/imaging with physical examination (percussion, palpation, motion testing), which is particularly important for verification of symptomatic VCFs in elderly patients. Taken together, these issues limit the generalizability and validity of the studies for real-world clinical management of VCFs. In order to address these limitations and generate new evidence for a relevant sub-population of patients with VCFs, investigators currently are recruiting patients to participate in VERTOS IV, which will compare vertebroplasty to sham procedure among patients with radiographically confirmed acute VCFs (≤ 6 weeks of pain).[8]	While there may be issues related to generalizability of the two sham controlled trials, they offer the best evidence regarding effectiveness. See also response to comment #27
	17	**Two published, randomized studies were powered to evaluate the safety and efficacy of kyphoplasty and vertebroplasty relative to NIM for the subset of patients with acute VCFs.** Prospective, randomized controlled studies that compared either vertebroplasty or kyphoplasty to NIM have shown these treatments to provide benefits in the way of improved pain relief and/or function relative to non-surgical management for well-defined population of patients with acute, non-malignant VCFs. In the randomized Fracture Reduction Evaluation (FREE) study, statistically significant improvements	The citations listed were published before the date of the WA HTA report (Aug 2010). The HTAS bases their guidance documents on reviews of the literature that utilize the highest standards of evidence based medicine. Studies are included or excluded

Stakeholder	#	Comment	Disposition
		in pain and function were sustained at 12 months for patients receiving kyphoplasty versus NIM.[9] In VERTOS II, a prospective multicenter RCT with 202 patients with acute VCFs, vertebroplasty provided statistically significant improvements in pain relief versus NIM at 12 months post-procedure (VAS 2.2 vs. 3.8; p = 0.014).[10] The incidence of new fractures was similar in both groups at the one-year follow-up time point (p = 0.28), and there were no serious complications or adverse events. Unlike the studies of vertebroplasty versus sham procedures, these two studies provide direct evidence for a well-defined population of patients suffering from acute VCFs (i.e., fractures ≤ 3 months of age), but cannot rule out response bias that may have occurred due to lack of blinding.	based on transparent, reproducible criteria; therefore the HTAS does not investigate individual studies. The HTAS assumes that the conclusions reached by the authors of these reviews weigh all the available evidence in accordance with the principles of evidence based medicine, and does not attempt to re-review the entire body of evidence to reach its own conclusions.
	18	**Professional guidelines on the appropriateness of vertebroplasty and kyphoplasty are varied and informed by distinct evidence.** Two professional guidelines were published *prior to availability* of the aforementioned VERTOS II study, which established the relative efficacy of vertebroplasty compared with NIM for acute VCFs. The American Academy of Orthopaedic Surgeons (AAOS) in 2010 released guidelines that vertebroplasty should not be considered for treatment of VCFs, a decision heavily influenced by the aforementioned sham-controlled studies.[11] In contrast, Appropriateness Criteria® published by the American College of Radiology (ACR) in 2010 indicate that both vertebroplasty and kyphoplasty may be appropriate for carefully selected patients after a failed trial of conservative measures or due to intolerance to conservative management.[12] The following vignettes within the ACR's Appropriateness Criteria® describe patients who may be considered for vertebroplasty or kyphoplasty after failure, or intolerance of, narcotics or non-steroidal anti-inflammatory drugs (NSAIDS): *"75-year-old woman with a documented old T9 compression fracture and 1-3-week old painful compression fracture of T12 without history of trauma. Patient has a history of gastric ulcer-related NSAIDs 2 years ago. Patient lives alone, is active, and the new fracture is impeding her independence. The older T9 fracture healed within 4-5 weeks."* *"80-year-old woman with a documented old T9 compression fracture treated by a percutaneous vertebroplasty 4 months ago. Now complains of a 5-week-old painful compression fracture of T12 without history of trauma. Patient is chronically constipated with history of cathartic abuse. Patient lives alone, is active, and the new fracture is impeding her independence."*	While the AAOS literature search was completed prior to the publication of VERTOS II, the WA HTA report was not, and VERTOS II was included in that review.
	19	**The HERC's coverage decision should be informed by the full body of literature, including new clinical studies published since completion of Washington State Healthcare Authority's systematic review.** The Washington State Healthcare Authority's coverage decision was based on an analysis dated November 4, 2010, suggesting that an updated systematic review of the literature is warranted. For example, two prospective, randomized studies comparing vertebroplasty to NIM for patients with acute (≤ 3 months)	Thank you for providing this reference. This unblinded study does not negate the findings of the two sham trials that had more appropriate control groups and found no differences in outcomes.

Stakeholder	#	Comment	Disposition
		and chronic (> 3 months) non-neoplastic VCFs were not yet published at the time of the Washington State HTA, and should be included in the HERC's review.[13, 14] Farrokhi et al. (2011) randomized patients to receive either vertebroplasty (n = 40) or NIM (n = 42).[13] Pain relief in the vertebroplasty group was significantly greater than that in the NIM group at 1 week, 2 months and 6 months ($p<0.05$), demonstrating an immediate and sustained benefit from vertebroplasty. Pain relief was maintained for the 36-month study duration, though between-group differences were not statistically significant beyond 12 months. Improvements in disability as measured by the Oswestry Disability Index (ODI) were statistically greater at all time points (1 week to 36 months) for patients in the vertebroplasty group relative to those in the NIM group. The incidence of new vertebral fractures was statistically higher among patients in the NIM arm relative to those in the vertebroplasty arm (13.3% versus 2.2%, $p < 0.01$). One patient who received vertebroplasty experienced cement leakage that resulted in lower-extremity pain and weakness subsequently alleviated with spinal decompression surgery.	
	20	In a single-center study in Spain, Blasco and colleagues randomized 125 patients to receive either vertebroplasty or NIM.[14] Patients in both treatment arms experienced reduced pain at all time points through 12-month follow up, though those in the vertebroplasty arm experienced superior improvement at the 2-month time point ($p = 0.035$). Significant improvement from baseline function, as measured by the Quality of Life Questionnaire of the European Foundation for Osteoporosis [Qualeffo-41] was observed at all time points for patients in the vertebroplasty arm and only at the 6-month time point for patients who received NIM. Vertebroplasty was associated with a significantly increased incidence of vertebral fractures (odds ratio [OR], 2.78; 95% confidence interval [CI], 1.02–7.62). Cement leakage occurred in 49% of vertebroplasty procedures, though these were not associated with immediate clinical sequelae.	Thank you for providing this reference. This unblinded study does not negate the findings of the two sham trials that had more appropriate control groups and found no differences in outcomes.
	21	A recently completed meta-analysis completed by Papanastassiou et al. (2012) sought to determine if differences in safety or efficacy exist between balloon kyphoplasty, vertebroplasty, and NIM for the treatment of VCFs.[15] A total of 27 studies were included, 9 of which compared vertebroplasty to NIM, 12 of which compared balloon kyphoplasty to vertebroplasty, and 6 of which compared balloon kyphoplasty to NIM. Key findings from that study are as follows: • Pain reduction for both kyphoplasty (-5.07/10 points) and vertebroplasty (-4.55/10) was statistically superior ($p < 0.01$) to that for NIM (-2.17/10), while no difference was found between kyphoplasty and vertebroplasty ($p = 0.35$). • Subsequent fractures occurred more frequently in the NIM group (22 %) compared with vertebroplasty (11 %, $p = 0.04$) and kyphoplasty (11 %, $p = 0.01$). • Patients with baseline fracture age less than 7 weeks experienced greater pain reduction (approximately 5.0 to 7.0 points) than those with VCFs treated later (approximately 2.3 to 4.5 points).	Based on this MA, KP appears to have similar efficacy to VP. Since VP does not have evidence of effectiveness compared to sham, one could conclude that KP similarly offers no benefit compared to sham.

Stakeholder	#	Comment	Disposition
		• Improvements QoL, as measured by the SF-36 Physical Component Summary (PCS) were superior for kyphoplasty versus vertebroplasty (p = 0.04), though the study's authors note that these differences should be interpreted with caution due to a limited number of studies and heterogeneity of pooled results.	
	22	**The HERC should seek to minimize variation to patient access to vertebroplasty and kyphoplasty in the state of Oregon and, like other public and private payers in the state, preserve access for the subset of refractory patients most likely to benefit from these procedures.** In 2011, Noridian Administrative Services (NAS), the Medicare Administrative Contractor (MAC) for Oregon and nine other states, released a coverage policy that provides access to vertebroplasty and kyphoplasty for a limited subgroup of patients suffering from acute VCF.[16] The following are among key coverage criteria in this policy, as informed by the full-body of literature and extensive public comment: • Vertebral compression fracture (VCF), with severe pain, refractory to conservative treatment and referable specifically to that site; • Patient's pain is documented to be severe (e.g., 7 or greater on 0 to 10 Visual Analog Scale [VAS]); • Fracture has been acceptably confirmed by plain film x-ray or by MRI, and results correlate unequivocally with the patient's pain; and • Fracture has been present for 4 months or less.	The HTAS makes its decisions based on evidence of effectiveness and harms, not on the basis of other payers' coverage policies. Limitations listed by the commenter confirmed in the LCD. Addition of the definition of when a compression fracture is not routine adds additional specificity. It is similar to the NAS coverage policy.
	23	DePuy Spine supports access to vertebroplasty and kyphoplasty for patients who are refractory to conservative medical management and who have met other professional society criteria. We encourage HERC's final coverage position to thoughtfully reflect the body of literature in its totality, including professional society treatment guidelines, Medicare and commercial payer policies, and not least the perspectives of patients in the state of Oregon.	HTAS does not find that the evidence supports the effectiveness of either of these procedures.
North American Spine Society Burr Ridge, IL	24	The North American Spine Society would like to take this opportunity to comment on the recently proposed draft coverage guidance from Oregon Health Evidence Review Commission (HERC) to revise their current coverage guidance for vertebral augmentation for osteoporotic compression and sacral fractures. NASS is a multispecialty medical organization dedicated to fostering the highest quality, evidence-based, ethical spine care.	Thank you for this information and for taking the time to comment. In the future, please provide full citations for studies referenced in your comments.
	25	In reviewing the draft coverage guidance, we recognize that HERC has modified the Washington State Health Care Authority Health Technology Assessment (HTA) for Vertebroplasty, Kyphoplasty and Sacroplasty that was published in 2010. NASS has provided comments previously on Vertebroplasty, Kyphoplasty and Sacroplasty to Washington State HTA on February 18, 2011 and Noridian on May 27, 2011.	Thank you for this information.
	26	NASS believes there should be several distinctions made when considering kyphoplasty, vertebroplasty	The HTAS appreciates this distinction but

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		and sacroplasty. The treatment of vertebral compression fractures by either kyphoplasty or vertebroplasty should be considered completely separately from sacroplasty for sacral insufficiency fractures. These are distinct anatomical and pathologic conditions. It is also imperative to distinguish cement augmentation procedures for neoplasm either primary or metastatic as a distinct and separate entity from osteoporotic compression fractures.	has chosen to address all three procedures in one guidance to reflect the scope of the evidence source. Although they are included in the same Coverage Guidance, each procedure is evaluated and recommendations are made separately.
	27	Within the comment letters to Washington State HTA and Noridian, we discussed the relevance of data published subsequent to the two New England Journal of Medicine (NEJM) articles (i.e. Kallmes et al, Buchbinder et al). NASS disagrees with the distinction in coverage policy between vertebroplasty and kyphoplasty. We certainly appreciate the decision to limit coverage of vertebroplasty based on the recent randomized controlled trials by Buchbinder et al and Kallmes et al published in the New England Journal of Medicine. However, these studies have legitimate weaknesses, particularly in the acuity of the fractures. NASS has published a systematic response to these two studies recently and appreciate the investigators' responses to our critique. Most notably, the two studies do not provide irrefutable evidence that vertebroplasty would not result in better outcomes compared to a sham procedure in truly acute fractures (i.e. 3 months old or less).	Citations not provided, but retrieved. Stated weaknesses include: • inclusion criteria included medical therapy for at least 4 weeks, resulting in a study of "healed fractures" • small enrollment (30-36% of eligible patients), limiting subgroup analysis • exclusion of patients with pathologic fractures • sham local anaesthetic injection is not an appropriate control • difference in cross over rates Authors responded to all of these weaknesses. It is not clear why the commenter makes the assumption that these two trials do not address acute fractures. In the Kallmes trial, patients could have pain for up to a year, but 38-44% had pain for 1-13 weeks, and for fractures of an uncertain age, marrow edema was required. In the Buchbinder trial, marrow edema was also required, and 32% of patients had pain duration less than 6 weeks.
	28	Second, the treatment effects in the NEJM studies about vertebroplasty were comparable to those found in the randomized controlled trials about kyphoplasty. Considering the inherent similarity of the two procedures, NASS believes that the same coverage rationale for kyphoplasty should be applied to vertebroplasty. The strongest support for this statement is the fact that kyphoplasty has been directly	HTAS agrees that the inherent similarity of KP and VP allows similar coverage decisions to be made. However, since VP does not have evidence of effectiveness compared

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		compared to non-operative treatment in a randomized trial, while vertebroplasty was not compared to non-operative treatment in the NEJM trials. Thus, there is a lack of evidence of the comparative effectiveness of the non-operative treatment prescribed in the current draft policy versus vertebroplasty. Previous prospective, nonrandomized evidence (Alvarez et al, 2006) suggests that vertebroplasty has advantages when performed within 6 weeks from fracture.	to sham, which is a study type that is less susceptible to bias, HTAS concludes that KP also does not have evidence of effectiveness. In addition, the Kallmes and Buchbinder trials are supported by the findings of an open randomized trial that did not show any benefit of vertebroplasty over usual care at 3 months (Rousing 2009). See comment #52 for description of study.
	29	More recently, the study published by Klazen et al (Lancet, 2010), a randomized prospective study comparing vertebroplasty to non-operative treatment, demonstrated significantly better results with the former. Inherent in its design, this study was not blinded, and thus can be critiqued in this regard in comparison to the blinded, sham experiments published in the NEJM. Relevant to the current discussion, this study augments the current knowledge about the efficacy/effectiveness of vertebroplasty for osteoporotic compression fractures.	This unblinded study does not negate the findings of the two sham trials that had more appropriate control groups and found no differences in outcomes.
	30	1. By using a non-operative treatment comparator, the study is more of a “real world” comparison of the two commonly used treatments, instead of the sham procedure used in the NEJM articles that included an anesthetic injection that may have some therapeutic effect.	Pain is an outcome that is highly subjective and susceptible to placebo effect. Use of a sham procedure is essential in this circumstance to identify true effect.
	31	2. The initial enrollment process detailed that 229 patients who could have been included in the study had spontaneous resolution of their pain and thus dropped out. This reinforces previously known knowledge about the favorable natural history of most patients with acute osteoporotic compression fractures.	This supports the rationale of the Kallmes and Buchbinder trials to require 4 weeks of medical therapy before enrollment.
	32	3. The inclusion criteria were much more stringent and specific than those used in the two NEJM studies, specifically that patients had a “visual analogue scale [pain] score of 5 or more; bone oedema of vertebral fracture on MRI; focal tenderness at fracture level…” prior to entry.	The significance of this fact, as it pertains to this evidence, is not clear.
	33	4. Fractures, on average, were more acute in the Klazen et al study compared to the NEJM studies.	The significance of this fact, as it pertains to this evidence, is not clear.
	34	At the NASS 26th Annual Meeting, November 2011 in Chicago IL, there were presentations showing both better hospital discharge outcomes and better survivorship in patients treated with vertebral cement augmentation. Edidin et al (Spine Journal 2011) looked at life expectancy following diagnosis of a vertebral compression fracture. The study utilized the Medicare database and looked at 100 percent of national inpatient and outpatient claims data from 2005–2008 for patients with a newly diagnosed vertebral compression fracture (VCF) identified using ICD-9-CM diagnosis codes. Using CPT-4 and ICD-9-CM	Both of these are retrospective database studies that are highly susceptible to bias. Gerling citation not provided.

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		procedure codes, patients were stratified into operated (kyphoplasty or vertebroplasty) and non-operated patients. Of the 858,978 patients with a newly diagnosed VCF were identified, including 119,253 kyphoplasty patients (13.9 percent) and 63,693 vertebroplasty patients (7.4 percent). Across all gender-age groups, the median life expectancy predicted by the parametric Weibull model was 2.2 to 7.3 years greater for operated than non-operated patients. Although in abstract form in The Spine Journal the results were published in the Journal of Bone and Mineral Research, 2011 Jul;26(7):1617-26. Gerling et al (Spine, 2011) in their review of Cement Augmentation of Refractory Osteoporotic Vertebral Compression Fractures came to similar conclusions. They reviewed a university hospital database to identify all participants treated with primary diagnosis of osteoporotic vertebral compression fracture between 1993 and 2006. They identified 46 patients treated with cement augmentation and 129 matched controls meeting inclusion criteria. Patients not differ with respect to age, sex, and comorbidities. "A significant survival advantage was found after cement augmentation compared with controls ($P < 0.001$; log rank), regardless of co-morbidities, age, or the number of fractures diagnosed at the start date ($P = 0.565$)." They concluded cement augmentation of refractory osteoporotic vertebral compression fracture improves survival for up to 2 years when compared with conservative pain management with bed rest, narcotics, and extension bracing, regardless of age, sex, and number of fractures or co morbidities.	
	35	Zambini et al (Spine Journal 2011) looked at hospital outcomes of both osteoporotic and neoplastic vertebral compression fracture treatment with kyphoplasty and vertebroplasty in the United States. The study utilized a national healthcare database, Nationwide Inpatient Sample (NIS), which is an annual survey of approximately 1,000 hospitals, containing data from 20 percent of all inpatient hospitalizations in the U.S. In a nationwide estimate of 86,810 neoplastic (74.7 percent emergent, 25.3 percent elective) and 370,933 non-neoplastic (77.5 percent emergent, 22.5 percent elective) patients were identified. Among the neoplastic group, 71.8 percent of elective and 23.0 percent of emergent patients underwent kyphoplasty, while for the non-neoplastic group, 69.4 percent of elective and 17.5 percent of emergent patients underwent kyphoplasty. The corresponding percent of patients that underwent vertebroplasty was 10.4 percent, 11.0 percent, 9.6 percent, and 9.0 percent, respectively. The remaining patients underwent non surgical management (NSM). After adjusting for all covariates, compared with NSM patients, kyphoplasty and vertebroplasty patients had significantly higher likelihood of routine discharge ($P > 0.001$) and lower risk of discharge to skilled nursing facility ($P > 0.001$). Compared with NSM patients, kyphoplasty and vertebroplasty patients also had lower risk of in-hospital mortality, pressure ulcer, pneumonia, and infection ($P > 0.029$), but had higher risk of complication of surgical procedure or medical care ($P > 0.001$). They concluded kyphoplasty and vertebroplasty patients have a higher likelihood of better in-hospital outcomes than NSM patients. These results while only currently in abstract form are compelling and NASS will continue to follow and review the final publication.	Database studies are considered a low level of evidence and highly susceptible to bias. Citation not provided.
	36	Considering the findings of the Lancet study, comparing them to those of the NEJM studies, in addition to	HTAS disagrees that the evidence supports

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		previously published, non-industry sponsored prospective comparative data (Alvarez et al, 2006), a number of points become apparent. 1. Vertebral augmentation can be considered in patients with pain that persists beyond six weeks despite non-operative care. This is supported by previous data that has demonstrated spontaneous pain relief in the majority of patients in the acute setting in this approximate time interval.	this recommendation.
	37	2. Vertebral augmentation via vertebroplasty or kyphoplasty should not be routinely considered in patients with fractures that are older than 3 months. This is supported by the findings of the two NEJM studies that failed to show that vertebroplasty was better than placebo in patients who mostly had fractures that were older than 3 months.	The NEJM studies also showed no effect on the 32-44% of patients who had fractures less than 3 months old.
	38	3. Within the appropriate time interval (6 weeks to 3 months from the onset of fracture), vertebral augmentation should be considered only if the patient has an MRI (or bone scan) that demonstrates bone edema within the fractured vertebral body and that this level corresponds to the site of pain upon physical examination (i.e. via percussing or palpating the patient's spinous processes). This can be confirmed with a plain radiograph with an opaque marker placed at the point of maximal tenderness.	The Buchbinder trial required evidence of marrow edema in all participants, and the Kallmes trial required it for any fracture of uncertain age. Even so, there was no evidence of efficacy of VP.
	39	4. Vertebral augmentation prior to six weeks should be considered only in those patients who are admitted to a hospital for management of pain associated with an osteoporotic compression fracture, are bed-bound secondary to pain, have failed to respond to non-operative inpatient care, and have satisfied the details outlined in criteria 3 (above). This is particularly true for patients with chemically-induced osteoporosis from medications such as corticosteroids or those with malignancy in whom bed rest could result in hypercalcemia.	The evidence does not support differential treatment based on the subgroups described by the commenter.
	40	5. We do not feel that a unilateral non-coverage determination is appropriate. NASS believes it would be far better to enforce appropriateness criteria to coverage of this procedure.	With the addition of a definition of when a compression fracture is not routine, the guidance is no longer a "unilateral non-coverage determination". Coverage is allowed for non-routine fractures, which is similar to appropriateness criteria.
	41	6. NASS currently agrees with a non-coverage policy for sacroplasty until further evidence is published.	Thank you for your comment.
	42	7. We strongly feel that vertebral cement augmentation for the treatment of pathological fractures (i.e. metastatic lesions, multiple myeloma) should be covered as a medically necessary procedure. The coverage policy should distinguish between vertebral cement augmentation for osteoporotic compression fractures, which should follow the above described appropriateness criteria, and pathological fractures, which should not, by nature of the disease, have a restricted time period of appropriate use. NASS hopes that you consider the above appropriate use criteria in development of a finalized policy for	HTAS did not include guidance on treatment of pathologic fractures due to limitations of the evidence base.

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		vertebral augmentation.	
Oregon Association of Orthopaedists, Inc. Portland, OR	43	The following comments are submitted on behalf of the Oregon Association of Orthopaedists, Inc., whose members practice throughout the state of Oregon. Additionally, I have practiced as a spine specialist in Oregon since 1988. We want to endorse the recommendation submitted by the North American Spine Society (NASS) that your guidance should reflect the distinctions between kyphoplasty, vertebroplasty and sacroplasty.	Thank you for this information and for taking the time to comment.
	44	We concur with the NASS' clinical practice guideline recommending kyphoplasty or vertebroplasty treatment for patients who present with an osteoporotic spinal compression fracture with 6 weeks to 3 months of symptoms. This procedure is only indicated before 6 weeks if the patient is incapacitated and essentially at bed rest with the pain. There should also be MRI imaging showing acute changes with correlating clinical signs and symptoms and no neurologic deficit. For these patients, kyphoplasty and vertebroplasty can significantly relieve pain and restore mobility. The NASS May 22, 2012 letter clearly summarized an accurate review of the literature supporting this position. The Washington State Health Care Authority HTAA 2010 policy is based on a less rigorous critique of the literature.	The NASS letter does not represent a thorough review of the literature, since no systematic search was done. It is not clear why the commenter believes that the WA HTA policy, which was based on a systematic review of the literature, is less rigorous.
	45	Your draft guidance does not distinguish between vertebroplasty and kyphoplasty. We concur with NASS' recommendation that your coverage guidance be amended to read: “Vertebroplasty and Kyphoplasty should be covered for routine osteoporotic compression fractures." The treatment of vertebral compression fractures by kyphoplasty or vertebroplasty is separate from sacroplasty for sacral insufficiency fractures. Thank you for your consideration of our comments.	HTAS does not believe the evidence for VP and KP is sufficiently strong to recommend coverage. HTAS appreciates the distinction between procedures but has chosen to address all three procedures in one guidance to reflect the scope of the evidence source. Although they are included in the same Coverage Guidance, each procedure is evaluated and recommendations are made separately.
Society of Interventional Radiology Fairfax, VA	46	The Society of Interventional Radiology (SIR) appreciates the opportunity to present our opinion on the above-referenced topic. The Society of Interventional Radiology (SIR) is a professional medical association that represents 5,000 members who are practicing in the specialty of vascular and interventional radiology. The Society is dedicated to improving public health through pioneering advances in minimally invasive, image-guided therapy. Our members are at the forefront of new and minimally invasive therapies to treat an array of diseases and conditions without surgery. Interventional radiology treatments have become first-line care for a wide variety of conditions and patients, including osteoporosis patients with spinal fractures,	Thank you for this information and for taking the time to comment. In the future, please provide full citations for studies referenced in your comments. (No citations were provided)

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		peripheral arterial disease, deep vein thrombosis, uterine fibroids, cancer and stroke patients.	
	47	The draft guidance of the Health Evidence Review Commission has indicated that vertebroplasty, kyphoplasty, and sacroplasty should not be covered for routine osteoporotic compression fractures. Although the HERC has made a clinical distinction between vertebroplasty and kyphoplasty, it is our opinion that for purposes of analysis, it is appropriate to consider these two procedures collectively. The clinical decision-making to diagnosis a vertebral compression fracture (VCF) is identical prior to either procedure, and patient outcomes for both procedures are similar. Therefore, in our analysis of the trials below, we will be considering kyphoplasty in addition to vertebroplasty together as treatment for osteoporotic vertebral fractures. In terms of sacroplasty, the SIR is actively working to coordinate research on this procedure, and although we are encouraged by the anecdotal reports, we concur that it should not be considered for routine fractures.	HTAS agrees that because of similarity of VP and KP procedures, considering the procedures together is reasonable. Since as the commenter states, "patient outcomes for both procedures are similar", and because the best evidence indicates the VP is not effective for osteoporotic VCFs, neither procedure should be covered.
	48	Within the past three years, results from five randomized controlled trials of percutaneous vertebral augmentation (PVA) vs. medical or sham therapy have been reported. The two largest trials totaling 502 patients reported better outcomes for patients treated with PVA vs. conservative medical therapy. Two smaller trials totaling 209 patients reported no improvement in outcomes vs. sham therapy. The smallest trial including 49 patients reported better outcomes at one month for patients treated with PVA vs. conservative therapy, but no improvement in outcomes at three or twelve months. The inclusion criteria, primary outcome measures, and results of each trial are briefly summarized below.	Please see disposition for individual trial summaries listed below.
	49	***Trial Summaries:*** The *Fracture Reduction Evaluation (FREE*) trial enrolled 300 patients over a 34 months period. One thousand twelve hundred seventy-nine patients were assessed, of whom 614 met eligibility criteria and 300 (49%) were enrolled. Inclusion criteria included one to three VCF, at least one of which had edema demonstrated by MRI and >15% height loss, and fracture age < three months. Although patients with multiple myeloma or metastases were included; only two such patients were enrolled in each treatment arm, so that this was effectively a study of osteoporotic VCF. Kyphoplasties were performed upon 149 patients; the remaining 151 patients were treated with medical therapy. Follow up evaluation included both clinical and radiographic evaluations up to one year after treatment. The primary outcome measure was the change in the SF-36 physical component score from baseline at one month. The primary outcome measure was significantly greater for those patients treated with vertebral augmentation ($p<0.001$). Secondary outcome measures of back pain and disability showed consistently superior and statistically significant results for the vertebral augmentation group up to one year after treatment, with the exception of opiate use at 12 months, which was not significantly different between the two groups. This was an industry sponsored study. In the FREE study, pain and narcotic use were also among several secondary outcomes. Graph showing	Citation not provided. This unblinded study does not negate the findings of the two sham trials that had more appropriate control groups and found no differences in outcomes.

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		significant differences in narcotic use between intervention and control only at the 3 month assessment (no differences at 1 week, 1 month, 6 months and 1 year). Referenced as: *Ashraf, Unpublished Presentation, 2010*	
	50	The ***Investigational Vertebroplasty Safety and Efficacy Trial (INVEST***) trial by Kallmes, et al enrolled 131 patients over a 50 month period. The original enrollment target was 250 patients, which was revised downward. One thousand eight hundred thirteen patients were assessed, of whom 431 met eligibility criteria and 131 (30%) were enrolled. Inclusion criteria included one to three VCF and fracture age of < twelve months. Patients with known malignancy were excluded. Patients with VCF of uncertain age could be enrolled if an MRI showed edema or a bone scan showed hyperactive uptake. Vertebroplasties were performed upon 68 patients and sham procedures upon 63 patients. The sham procedure included superficial and deep injection of local anesthetics and mixing of cement within the operating room to simulate a vertebral augmentation procedure, as this was to be a blinded trial. Follow up consisted of interviews conducted in person at one and twelve months and by telephone at three and fourteen days and three months, and radiographs at twelve months. Physical reevaluation was not performed as part of the follow up protocol. The primary outcome measure was the change in the modified Roland-Morris Disability Questionnaire and average pain intensity at one month. The primary outcome measures were not significantly different between the two patient groups at one month. A secondary outcome measure was clinically meaningful improvement in pain at one month; 64% of patients receiving vertebral augmentation achieved this vs. 48% of controls (p=0.06). This outcome is particularly notable because the *p* value is so close to reaching statistical significance. Had the original enrollment target been met and with the same distributions of patient outcomes, this study would have shown statistically significant positive results for clinically meaningful pain improvement at one month for the vertebral augmentation arm. The SIR commented on this trial in detail in a letter to the *New England Journal of Medicine.*	The assumption that if the original enrollment target had been met, the study would have shown statistically significant positive results cannot be supported. The commenter assumes that VP patients would have more favorable outcomes. Of note, study groups did not differ significantly on ANY primary or secondary outcomes, including pain and QOL. While there was indeed a trend seen in clinically meaningful pain improvement in the VP group, no such trend was seen in physical disability related to back pain outcome (P=0.99). This study had 80% power to detect important differences in the primary outcome measures (a 3 point difference between groups on the Roland-Morris Disability Questionnaire, or a 1.5 point difference on patient rating of back pain intensity on a scale of 1-10).
	51	The randomized trial of vertebroplasty for painful osteoporotic fractures reported by Buchbinder et al enrolled 78 patients over a 54 month period. Four hundred sixty eight patients were assessed, of whom 219 met eligibility criteria and 78 (36%) were enrolled. Inclusion criteria included one or two VCF, fracture age of < twelve months, and MRI showing edema and/or a fracture line within the target vertebrae. Patients with known malignancy were excluded. Vertebroplasties were performed upon 38 patients and sham procedures upon 40 patients. The sham procedure was essentially the same as that used in the INVEST trial; this was also intended to be a blinded trial. Follow up consisted of mailed questionnaires at one week and one, three, and six months. As with the INVEST trial, physical reevaluation was not performed as part of the follow up protocol. The primary outcome measure was the score for overall pain over the course of the previous week at three months. The investigators reported that overall pain was not significantly different between patients undergoing vertebral augmentation and control subjects at any of the measured time points. This study was partially supported by industry.	Thank you for providing this study detail. Please provide citation in the future.

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	52	Rousing et al reported upon forty-nine patient treated with vertebroplasty or conservative therapy for osteoporotic VCF over a period of 84 months. The numbers of patients screened and assessed were not reported, so that the percentage of eligible patients enrolled remains unknown. Inclusion criteria included one to three VCF and fracture age < eight weeks. If more than one fracture was present, either edema on MRI or hyperactive uptake on a bone scan was used to determine which fractures were subacute. Forty patients were enrolled with pain of < two weeks duration. Patients with known malignancy were excluded. Vertebroplasties were performed upon 25 patients; the remaining 24 patients were treated with medical therapy. Follow up evaluation included both clinical and radiographic up to one year after treatment. The primary outcome measures were pain relief at three and twelve months as measured by the visual analog score (VAS). The investigators reported no statistically significant differences between the vertebral augmentation patients and the controls for pain or various functional measurements at three or twelve months. Supplementary analysis of pain at one month post treatment was, however, significantly different between the two groups; the mean VAS for the vertebral augmentation group (3.5) was significantly less than that for the controls (6.4) (p<0.01).	The outcome for which a significant effect was found (pain at 1 month) was not prespecified, and was not published in the original paper. Not clear if this is unpublished information, since no citation provided. Of note, there was a significant increased risk of new VCFs in the intervention group (RR=2.9).
	53	***VERTOS II*** On August 10, 2010, the results of the VERTOS II open-label randomized control trial were published online in *The Lancet.* VERTOS II provides markedly different results from Kallmes and Buchbinder. The VERTOS II trial enrolled 202 patients over a 31 month period. Nine hundred thirty-four patients were screened, of whom 431 met eligibility criteria and 202 (47%) were enrolled. Inclusion criteria included one to three VCF, >15% vertebral height loss, bone edema on MRI, and fracture age of < six weeks. Patients with known malignancy were excluded. Vertebroplasties were performed upon 101 patients and the other 101 patients were treated with medical therapy. Follow up evaluation included both clinical and radiographic evaluations and patient questionnaires up to one year after treatment. The primary outcome measures were pain relief at one month and one year as measured by the visual analog score (VAS). Statistically significant improved pain relief was reported for patients treated with vertebral augmentation vs. controls at all measured time points from one day through one year. Secondary analyses included positive proof of cost-effectiveness for vertebral augmentation. This study was partially supported by industry.	Citation not provided. This unblinded study does not negate the findings of the two sham trials that had more appropriate control groups and found no differences in outcomes.
	54	In their findings, the VERTOS II authors note that vertebroplasty resulted in better pain relief after one, three, and six months and one year (*P*<0.001, *P*<0.001, *P*=0.025, and *P*=0.014, respectively) over conservative treatment. No serious complications or adverse events were reported. The incidence of new compression fractures was lower in the vertebroplasty group, although not significantly different from the conservative care (control) group.	Citation not provided. This unblinded study does not negate the findings of the two sham trials that had more appropriate control groups and found no differences in outcomes.
	55	The VERTOS II study additionally notes that vertebroplasty appears to be a cost effective treatment. The	Since evidence of effectiveness has not

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		"adjusted trial-based incremental cost-effectiveness ratio for vertebroplasty, as compared to conservative treatment, was €22,685 per QALY gained." While we concur that many VCFs heal on their own through conservative treatment, the long term costs of conservative care, pain narcotics, risks of deep vein thrombosis, pressure sores, and often the need for skilled nursing (or extensive family care) are all potential consequences of conservative care.	been established, it is inappropriate to calculate an ICER.
	56	***Analysis of the Trials*** Many controversial points were raised about the INVEST and Buchbinder et al trials that reported unexpectedly negative results. Whether a proper control arm for a vertebral augmentation study requires a sham procedure and whether such a sham procedure is ethical could be debated endlessly. Valid arguments can be made that either sham or medical treatment are acceptable and ethical controls. Whether appropriate follow up absolutely necessitates a physical examination might also be argued without resolution. The fragility of the statistics resulting from the INVEST trial's reduced enrollment has also been questioned. Debate continues about the alleged disparities between the patients enrolled into the INVEST, Buchbinder et al and Rousing et al trials vs. "real world" patients. None of these issues has any remaining significance now that data from all five trials has been published. Controversy and conflicting results permeate all aspects of medicine. One must focus upon both the quality and the quantity of evidence.	HTAS disagrees that controversy and conflicting results permeate all aspects of medicine, but agrees that when results are conflicting, is it imperative to focus on both the quality and the quantity of the evidence.
	57	The principle limitation of the VERTOS II study is the lack of a sham control. However, this deserves closer scrutiny. We in the medical provider community would comment that it is extremely difficult to recruit patients to a sham controlled trial, and it may not be feasible to conduct a study of this type. Of note, in the Kallmes study, many US institutions would not endorse sham trials and many investigators remain wary of sham trials. In fact, in recent presentations, Dr. Kallmes has stopped using the term sham for patients that receive medial branch block and has used the term "control intervention."	The lack of a sham control results in serious susceptibility to bias in this trial. Both sham controlled trials had sufficient power to detect a difference, and because they were completed, would seem to contradict the statement that such trials are not feasible.
	58	Therefore, the VERTOS II study represents the highest quality of data regarding percutaneous vertebroplasty for symptomatic vertebral compression fractures. The strength of this study is the on-going positive benefit at the one year follow up period. In addition to long term pain relief, this study demonstrated very rapid pain relief. Short term pain outcome is vitally important in and of itself as patients with disabling acute pain are at significant risk of further complications and are not candidates for long term conservative therapy.	HTAS disagrees that VERTOS II is the highest quality data. This was an unblinded study, which any evidence-based text book would identify as a lower quality of evidence than a blinded trial.
	59	***Failed Conservative Treatment: What is the Threshold?*** In the treatment of an osteoporotic VCF, a common question that is confronted is how long should conservative medical management be employed before considering an interventional procedure? We would purport that assigning strict time limits to such a clinical decision would be problematic, and is best made on a case-by-case basis. The concept of a mandatory period of medical management prior to PVA	Defining a period for conservative treatment is not needed for procedures that are not effective.

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		did not originate within the medical literature. The first published reference regarding this appears to be within an FDA guidance document published in 2004, "Clinical Trial Considerations: Vertebral Augmentation Devices to Treat Spinal Insufficiency Fractures". The document states that trials should include "patients that (sic) have failed various, currently available conservative treatments, after a sufficient time period when fractures would be expected to heal, generally eight weeks, or more." This document does not identify the author(s). The document has an expiration date of May 31, 2007, but has never been updated to our knowledge. Accordingly, it is imperative that the decision to treat a VCF patient with a procedure must be made based on the presentation of each patient. As Klazen and her co-authors have speculated on the appropriateness of a medical management time period, they have also noted that "waiting 6 months in all patients can cause unnecessary pain and lost days for work and normal activity, when treatment with vertebral augmentation can provide almost immediate pain relief."	
	60	Defining what constitutes failure of conservative medical therapy for patients with VCF must integrate the patient's pain level, their response to analgesics, and their functional status including the impact of the medical therapies employed. Pain is, of course, subjective and individual, so that a certain level on a scale such as the VAS would be inadequate. However, pain that prevents ambulation or physical therapy represents a rather simple and dependable measure of both "severe" pain and significant disability. In addition, prompt restoration of ambulatory status or return to best prior sub-ambulatory status is clinically important. Even in the absence of other pathology, prolonged bed rest of greater than 48 hours duration clearly represents a significant hazard to the patient. For patients who were non –ambulatory prior to their incident VCF, a significant reduction in prior physical functional status should be considered the equivalent of being rendered non-ambulatory.	Defining a period for conservative treatment is not needed for procedures that are not effective.
	61	***Summary:*** In sum, the two largest trials with the highest rates of patient enrollment and inclusion criteria generally viewed as being similar to typical "real world" patients have demonstrated benefits for vertebral augmentation persisting through one year post intervention. One of the smaller trials (Rousing et al) also demonstrated benefit from vertebral augmentation up to one month post intervention, but not beyond this point. The INVEST trial reported a very strong trend toward clinically meaningful improvement in pain for the vertebral augmentation group at one month. This finding narrowly missed achieving clinical significance despite the reduced number of patients enrolled vs. the original goal. Only the trial by Buchbinder et al failed to show that vertebral augmentation was beneficial at one month post intervention. A long-term (one year) benefit for vertebral augmentation was proven in the two largest trials; with total patient enrollment double that of the remaining three trials. Even if one were to accept the results from the INVEST and Buchbinder trials without question, a premise unacceptable to many	The two largest studies referred to by the commenter are unblinded, and of lower quality than the Kallmes and Buchbinder trials. HTAS disagrees that Buchbinder was the only trial to show lack of benefit at 1 month, since Kallmes found study groups did not differ significantly on ANY primary or secondary outcomes, including pain and QOL. It is not clear why unbiased physicians would have difficulty accepting the INVEST and Buchbinder trials, both published in the NEJM.

Stakeholder	#	Comment	Disposition
		physicians, the overall message remains clear. Therefore, after carefully weighing all of the available evidence, we must conclude that vertebral augmentation of osteoporotic VCF is very clearly beneficial in the short term and likely also in the long term, as well as being cost effective.	
	62	Prolonged arbitrary time periods of medical management do not have a role in the current treatment of patients with VCF. It is clear from the available clinical data that early intervention for patients severely affected by VCF produces better clinical outcomes and that this is also cost effective.	HTAS disagrees that early intervention with VP produces better clinical outcomes, since the available evidence does not support that conclusion.
	63	In sum, we would ask the HERC to carefully review all of the evidence, as well as to consider the professional opinions of physicians who are treating osteoporotic fracture patients every day. If denied access to spinal augmentation procedures, we believe that Oregonians would not have available to them a procedure that we believe should be part of a physician's treatment options. I thank the HERC for the opportunity present our views. If desired, several of our members in Oregon would be pleased to go into further details about our position.	Thank you for your comment. HTAS has reached a different conclusion after examining the available evidence.
Neurological Surgeon Portland, OR	64	The vertebroplasty/kyphoplasty topic is the most difficult of the three. The two randomized, controlled, blinded trials of vertebroplasty showed no advantage over sham surgery, but in fact, both groups were considerably better postoperatively. Therefore, some have interpreted the data not as showing that the procedure is ineffective, but showing that it works for reasons we do not understand. The Mayo Clinic is currently conducting further trials to try to determine why the sham surgery was so effective. There has also been much criticism of the methods of the studies. For example, the procedures were all done by radiologists, not spine surgeons, raising the question of whether the patients were properly screened for surgery, etc. Of course, criticizing and arguing against well done studies that show a result you do not want to see is sometimes inappropriate and must be viewed cautiously.	Thank you for this information, and for providing your perspective.
	65	My own practice is based on more than 8 years of experience with kyphoplasty. In over 100 procedures, I have found it to be about 80% effective in producing dramatic and rapid relief of pain. I have had a number of patients have 5 or more kyphoplasties over several years. I do not believe they would continue to undergo repeated procedures if the effect was not significant. Many patients have told me that they had to fail prolonged conservative management to get to their first kyphoplasty, so when they fractured another vertebra, they demanded immediate surgery without a waiting period, again indicating a strong belief in the effectiveness of the procedure. For patients hospitalized with unbearable pain, kyphoplasty has allowed mobilization and discharge, which must result in some cost savings over prolonged hospitalization or a nursing home. Many of these patients are in agony and without other effective treatment options.	Thank you for this information, and for providing your perspective.
	66	My own preference would be for the following: 1. Patients hospitalized because of unbearable pain from a new osteoporotic or malignant compression	Thank you for your comment. Definition of non-routine fracture matches your

Stakeholder	#	Comment	Disposition
		fracture and whose pain cannot be rapidly brought under control to the point of discharge to home should be allowed to have immediate kyphoplasty.	recommendation.
	67	2. Patients with a new osteoporotic or malignant compression fracture who have failed 6-12 weeks of appropriate conservative management (pain medication, bracing, Miacalcin, TENS, PT, etc) with continuing need for potent narcotics, severe narcotic side effects (sedation, confusion, constipation, respiratory suppression), and/or impaired mobility should be allowed to have an elective kyphoplasty. I realize that this is contrary to the draft recommendations, but I hope to allow some room for the procedure as some patients really do need more than medical management.	See comment #66.

Section 8

New Discussion Items Part 2

Acupuncture for Knee Osteoarthritis

Question: Should acupuncture be added for treatment of knee osteoarthritis?

Question source: Laura E. Ocker, LAc, President, OAAOM

Issue: Acupuncture is currently on the Prioritized List for treatment of various conditions, including drug addiction, HIV, depression following stroke, several pregnancy related conditions, low back pain, migraine and tension headaches. There is a guideline limiting use of acupuncture for several of these conditions. The Oregon Association of Acupuncture and Oriental Medicine (OAAOM) and the Oregon College of Oriental Medicine (OCOM) are jointly requesting that acupuncture be considered for pairing with several chronic pain conditions, including neck pain, osteoarthritis, and shoulder pain.

Current Prioritized List placement

715.95 (Osteoarthrosis, unspecified whether generalized or localized, lower leg) is currently on lines 384 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE Treatment ARTHROPLASTY/ RECONSTRUCTION and 489 OSTEOARTHRITIS AND ALLIED DISORDERS Treatment MEDICAL THERAPY, INJECTIONS

Acupuncture (CPT 97810-4) is currently on lines 1,5,6,15,68,70,212,400,435,562,563.

Evidence

1) **Vickers 2012**; patient level meta-analysis of high quality RCTs
    a. N=9 studies for osteoarthritis
        i. N=8 for knee pain, N=1 for hip pain)
    b. Acupuncture was superior to both sham and no acupuncture control for each pain condition (*P*<.001 for all comparisons).
    c. Osteoarthritis: pain reduced 0.16 (95% CI, 0.07-0.25) vs sham control and 0.57 (95% CI, 0.50-0.64) vs no acupuncture control
2) **NICE 2008,** systematic review of acupuncture for osteoarthritis (knee, hip, thumb)
    a. The results from acupuncture studies are mixed.
    b. The studies which have shown superiority of acupuncture over placebo have shown this only in the short term (6–12 weeks). At 26 weeks there are few studies, and overall they do not support a benefit over placebo. It therefore seems likely that acupuncture can provide short- to medium-term relief for some people.
    c. Acupuncture of peripheral joints appears safe.
    d. The health economic literature is limited and not based in the UK NHS or similar healthcare systems. The incremental cost-effectiveness ratio for acupuncture is often higher than the threshold of £20–£30K per QALY that is typically quoted as what the NHS can afford. However, there is considerable uncertainty about this

estimate because of the limitations in the data. However, electro-acupuncture was consistently above the threshold of cost effectiveness.

e. Recommended against coverage for electro-acupuncture, but made no recommendation on traditional acupuncture

3) **Manheimer 2010**, Cochrane systematic review of acupuncture for peripheral osteoarthritis
    a. N=16 trials, 3498 patients
        i. N=12 OA of knee
        ii. N=3 OA of hip
        iii. N=1 OA of hip or knee
    b. In comparison with a sham control, acupuncture showed statistically significant, short-term improvements in osteoarthritis pain (standardized mean difference -0.28, 95% confidence interval -0.45 to -0.11; 0.9 point greater improvement than sham on 20 point scale; absolute percent change 4.59%; relative percent change 10.32%; 9 trials; 1835 participants) and function (-0.28, -0.46 to -0.09; 2.7 point greater improvement on 68 point scale; absolute percent change 3.97%; relative percent change 8.63%); however, these pooled short-term benefits did not meet our predefined thresholds for clinical relevance (i.e. 1.3 points for pain; 3.57 points for function) and there was substantial statistical heterogeneity. Additionally, restriction to sham-controlled trials using shams judged most likely to adequately blind participants to treatment assignment (which were also the same shams judged most likely to have physiological activity), reduced heterogeneity and resulted in pooled short-term benefits of acupuncture that were smaller and non-significant.
    c. In comparison with sham acupuncture at the six-month follow-up, acupuncture showed borderline statistically significant, clinically irrelevant improvements in osteoarthritis pain (-0.10, -0.21 to 0.01; 0.4 point greater improvement than sham on 20 point scale; absolute percent change 1.81%; relative percent change 4.06%; 4 trials;1399 participants) and function (-0.11, -0.22 to 0.00; 1.2 point greater improvement than sham on 68 point scale; absolute percent change 1.79%; relative percent change 3.89%).
    d. In a secondary analysis versus a waiting list control, acupuncture was associated with statistically significant, clinically relevant short-term improvements in osteoarthritis pain (-0.96, -1.19 to -0.72; 14.5 point greater improvement than sham on 100 point scale; absolute percent change 14.5%; relative percent change 29.14%; 4 trials; 884 participants) and function (-0.89, -1.18 to -0.60; 13.0 point greater improvement than sham on 100 point scale; absolute percent change 13.0%; relative percent change 25.21%).
    e. In the head-on comparisons of acupuncture with the ’supervised osteoarthritis education’ and the ’physician consultation’ control groups, acupuncture was associated with clinically relevant short- and long-term improvements in pain and function. In the head on comparisons of acupuncture with ’home exercises/advice leaflet’ and ’supervised exercise’, acupuncture was associated with similar treatment effects as the controls. Acupuncture as an adjuvant to an exercise based

physiotherapy program did not result in any greater improvements than the exercise program alone.

f. **Authors' conclusions** Sham-controlled trials show statistically significant benefits; however, these benefits are small, do not meet our pre-defined thresholds for clinical relevance, and are probably due at least partially to placebo effects from incomplete blinding. Waiting list-controlled trials of acupuncture for peripheral joint osteoarthritis suggest statistically significant and clinically relevant benefits, much of which may be due to expectation or placebo effects.

4) **Hopton 2010,** review of pooled data from meta-analyses
   a. N=4 meta-analyses
   b. The collated results indicate that in the short term, acupuncture provided statistically significant effective pain relief compared with sham controls in…chronic osteoarthritis of the knee17–20 (with the caveat that this holds provided outcomes were measured after treatment was completed—one inconclusive outcome was based on a 4-week time point, well before rial treatments ended)…These differences remained statistically significant in the longer term at 6 to 12 months, for knee pain
   c. In general, effect sizes (standardized mean differences) were found to be relatively small.
5) **Kwon 2006**, meta-analysis
   a. N=18 RCTs (10 manual acupuncture, 8 electroacupuncture)
   b. Overall, ten studies demonstrated greater pain reduction in acupuncture groups compared with controls. The meta-analysis of homogeneous data showed a significant effect of manual acupuncture compared with sham acupuncture (standardized mean difference 0.24, 95% confidence interval 0.01–0.47, P¼0.04, n¼329), which is supported by data for knee OA. The extent of heterogeneity in trials of electro-acupuncture prevented a meaningful meta-analysis.

Specialty society recommendations

1) American College of Rheumatology (ACR), (**Hochberg 2012**)
   a. Conditionally recommend acupuncture for knee OA
      i. Only when the patient with knee osteoarthritis (OA) has chronic moderate to severe pain and is a candidate for total knee arthroplasty but either is unwilling to undergo the procedure, has comorbid medical conditions, or is taking concomitant medications that lead to a relative or absolute contraindication to surgery or a decision by the surgeon not to recommend the procedure.

Other policies

1) Aetna 2012
   a. Covers acupuncture for treatment of pain from osteoarthritis of the knee or hip (adjunctive therapy; if no clinical benefit is appreciated after 4 weeks, then the treatment plan should be reevaluated)

2) Cigna 2012
   a. Covers acupuncture for neck pain and osteoarthritic knee pain

Acupuncture for Knee Osteoarthritis

Summary
Treatment of osteoarthritis of the knee with acupuncture appears to have some evidence to support use for short term pain relief in limited circumstances.

Recommendations:

1) Add acupuncture (CPT 97810-4) to line 489 OSTEOARTHRITIS AND ALLIED DISORDERS Treatment MEDICAL THERAPY, INJECTIONS
2) Modify the acupuncture guideline as shown in the separate document titled ~~–~~Acupuncture Guideline" and excerpted below
    a. Limit coverage to the patients with recommended treatment as outlined by the ACR
    OR
    b. Add coverage for knee osteoarthritis with no limitations
        i. Preferred by HERC staff

Line 489 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on line 489 for treatment of osteoarthritis of the knee only when the patient has chronic moderate to severe pain and is a candidate for total knee arthroplasty but either is unwilling to undergo the procedure, has comorbid medical conditions, or is taking concomitant medications that lead to a relative or absolute contraindication to surgery or a decision by the surgeon not to recommend the procedure.

Alternative:
Acupuncture pairs on line 489 for treatment of osteoarthritis of the knee only, when referred, for up to 12 sessions.

Oregon Association of Acupuncture and Oriental Medicine
OAAOM PO BOX 14615, PORTLAND, OR 97293-0615 http://www.oaaom.com/

1 January 2013

Catherine Livingston, MD, MPH and Ariel Smits, MD, MPH, Medical Directors
cc: Darren Coffman, Director
Health Evidence Review Commission
General Services Building 1225 Ferry Street SE, 1st Floor
Salem, OR 97301

RE: Petition to include acupuncture on the Prioritized List paired with lines with diagnosis codes for chronic pain, especially neck pain, osteoarthritis, and shoulder pain

Dear Dr. Livingston and Dr. Smits:

Please accept the included evidence, submitted by the Oregon Association of Acupuncture and Oriental Medicine (OAAOM) and the Oregon College of Oriental Medicine (OCOM), addressing the effectiveness of acupuncture for several chronic pain conditions, including neck pain, osteoarthritis, and shoulder pain.

Links to full text are provided for most studies cited. There are only five exceptions. Three studies are included as attachments (highlighted in yellow). Two other studies are listed with links to abstracts, and the full texts will be provided by the OCOM Research Department if needed.

Please do not hesitate to contact us if we can be of further assistance. Thank you.

Sincerely,

Laura E. Ocker, LAc, President, OAAOM
Ben Marx, LAc, Research Associate, OCOM Research Department

THE EVIDENCE

I. Chronic Pain (back pain, neck pain, osteoarthritis, chronic headache, shoulder pain)

Of all the studies submitted in this packet, this first Meta-analysis (Vickers 2012) is the most conclusive and most recent.

1) **Title:** *Acupuncture for Chronic Pain: Individual Patient Data Meta-analysis*
Authors: Vickers, AJ et. al.
Published Online: September 10, 2012
Journal: *Arch Intern Med.* 2012;172(19):1-10
Full Text PDF: Attached
Link to Abstract:
http://www.ncbi.nlm.nih.gov/pubmed?term=vickers%20acupuncture%20for%20chronic%20pain%202012

Purpose: *to determine the effect size of acupuncture for four chronic pain conditions: back and neck pain, osteoarthritis, chronic headache, and shoulder pain.*

Methods: *Individual patient data meta-analyses were conducted using data from 29 of 31 eligible RTCs, with a total of 17,922 patients analyzed.*

Results: *Acupuncture was superior to both sham and non-acupuncture control for each pain condition ($p<.001$ for all comparisons).*

Comments:

This meta-analysis is included as it was very recently published (September 2012), of high quality, and conclusive.

The NIH, Center for Complementary and Alternative Medicine (CCAM) website was updated on September 10, 2012 with this statement about the review: "A recent NCCAM-funded study, employing individual patient data meta-analyses and published in the *Archives of Internal Medicine*, provides the most rigorous evidence to date that acupuncture may be helpful for chronic pain."

http://nccam.nih.gov/research/results/spotlight/091012

How this analysis differs from previously published reviews:

Benefits of using individual patient data (a different strategy employed from previously published acupuncture reviews for chronic pain), from p. E1 last paragraph: *Individual patient data meta-analysis are superior to the use of summary data in meta-analysis because they enhance data quality, enable*

different forms of outcome to be combined, and allow use of statistical techniques of increased precision.

Comparison with other studies (why this meta-analysis that may provide more conclusive results than prior reviews), from p. E7, bottom of first column: *Many prior systematic reviews of acupuncture for chronic pain have had liberal eligibility criteria, accordingly included RTCs of low methodologic quality, and then came to the circular conclusion that weaknesses in the data did now allow conclusions to be drawn. Other reviews have not included meta-analyses, apparently owing to variation in study end points.*

How the study results break down in common terms:

From p. E4, third column at the top: If response were defined in terms of a pain reduction, response rates would be approximately 30% pain reduction for the non-acupuncture group, 42.5% pain reduction for the sham-controlled acupuncture, and 50% pain reduction with true acupuncture.

II. Neck Pain

The following synopsis was compiled and organized in June of 2012 by Charlie Cannon and Kate Haber. At the time they were both Masters students enrolled in the Oregon College of Oriental Medicine.

Please also refer to the first meta-analysis presented in this packet, Vickers 2012, to support the effectiveness of acupuncture to address neck pain.

For more information, please see attachment: *Acupuncture for the Treatment of Cervical Pain, An Evidence Based Assessment*, prepared by Ryan Milley, October 2010 for the Society of Acupuncture Research.

1. Title: Randomized Controlled Trials of Acupuncture for Neck Pain: Systematic Review and Meta-Analysis
   Authors: Li-Min Fu, Ju-Tzu Li, and Wen-Shuo Wu
   Year Published: 2009
   Citation: Fu, L.M., Li, J.T., Wu, W.S. (2009). Randomized Controlled Trials of Acupuncture for Neck Pain: Systematic Review and Meta-Analysis. *Journal of Alternative and Complementary Medicine* 15(2):133-145.
   Please contact Ben Marx, OCOM Research Dept. for full text: bmarx@ocom.edu
   Link to abstract: http://www.ncbi.nlm.nih.gov/pubmed/19216662

Objectives: The objectives of this study were to assess the effectiveness and efficacy of acupuncture in the treatment of neck pain.

Data sources: The following computerized databases were searched from their inception to January 2008: MEDLINE (PubMed), ALT HEALTH WATCH (EBSCO), CINAHL, and Cochrane Central.

Review methods: Systematic review and meta-analysis were conducted on randomized controlled trials of acupuncture for neck pain. Two (2) reviewers independently extracted data concerning study characteristics, methods, and outcomes, as well as performed quality assessment based on the adapted criteria of Jadad.

Results: Fourteen (14) studies were included in this review. Meta-analysis was performed only in the absence of statistically significant heterogeneity among studies that were selected for testing a specific clinical hypothesis. While only a single meta-analysis was done in previous reviews, this review performed nine meta-analyses addressing different clinical issues. Seven out of nine meta-analyses yielded positive results. In particular, the meta-analysis based on the primary outcome of short-term pain reduction found that acupuncture was more effective than the control in the treatment of neck pain, with a pooled standardized mean difference (SMD) of _0.45 (95% confidence interval [CI], _0.69 to _0.22). Moreover, the meta-analysis with a pooled SMD of _0.53 (95% CI, _0.94 to _0.11) showed that acupuncture was significantly more effective than sham acupuncture for pain relief. However, there was limited evidence based on the qualitative analysis of the trial data to support the above conclusions. We provided a detailed analysis on the issue of heterogeneity of the studies involved in meta-analysis and examined the consistencies and inconsistencies among the present review and two other reviews conducted previously.

Conclusions: The quantitative meta-analysis conducted in this review confirmed the short-term effectiveness and efficacy of acupuncture in the treatment of neck pain. Further studies that address the long-term efficacy of acupuncture for neck pain are warranted.

2. Title: Acupuncture for neck disorders (Review)
   Authors: Kien Trinh, Nadine Graham, Anita Gross, Charles H Goldsmith, Ellen Wang, Ian D Cameron, Theresa M Kay
   Year Published: 2006
   Citation: Trinh, K., et al. (2006). Acupuncture for neck disorders. Cochrane Database Syst Rev, 3:CD004870.
   Link to full text:
   https://docs.google.com/viewer?a=v&q=cache:flh30SaeDMEJ:www.thecochranelibrary.com/userfiles/ccoch/file/Acupuncture_ancient_traditions/CD004870.pdf+Trinh,+K.,+et+al.+(2006).+Acupuncture+for+neck+disorders.+Cochrane+Database+Syst+Rev,+3:CD004870.&hl=en&gl=us&pid=bl&srcid=ADGEEShYhQAwG_RQm-YgmfBQ2Kt4FoDtRJv4m0M-flhxmX4RGvR8DzU_VIeBm4QcDAHPS6r6xs6sS6bcWRRMusxVDwmW4BAXkXwSPBnoWm4I3dBAQZ2GgkHAby25sCPphbH9YjZhWZRV&sig=AHIEtbRIlN24O6Bg9jWHiDTHhG_Az2FZLw

Objectives: To determine the effects of acupuncture for individuals with neck pain.

Data sources: Any published trial using randomized (RCT) or quasi-randomized (quasi-RCT) assignment to intervention groups, either in full text or abstract form, were included.

Review methods: Two reviewers made independent decisions for each step of the review: article inclusion, data abstraction, and assessment of trial methodological quality. Study quality was assessed using the Jadad criteria. Consensus was used to resolve disagreements. When clinical heterogeneity was absent, we combined studies using random-effects meta-analysis models.
Results: There were no trials that examined the effects of acupuncture for acute or subacute pain, but there were 10 trials which examined treatments for chronic neck pain. Overall, methodological quality had a mean of 2.3/5 on the Jadad Scale.

Conclusions: There is moderate evidence that acupuncture relieves pain better than some sham treatments, measured at the end of the treatment. There is moderate evidence that those who received acupuncture reported less pain at short term follow-up than those on a waiting list. There is also moderate evidence that acupuncture is more effective than inactive treatments for relieving pain post-treatment and this is maintained at short-term follow-up.

Neck Pain: Medium Quality Evidence

"There is one additional trial that I think is relevant. It is a well-conducted study from the Memorial Sloan-Kettering Cancer Center, and because it was published in 2010 it was not included in the analyses of the above Systematic Reviews." - Ben Marx, LAc, OCOM Research Department

3. Title: Acupuncture for pain and dysfunction after neck dissection: results of a randomized controlled trial
   Authors: David G. Pfister, Barrie R. Cassileth, Gary E. Deng, K. Simon Yeung, Jennifer S. Lee, Donald Garrity, Angel Cronin, Nancy Lee, Dennis Kraus, Ashok R. Shaha, Jatin Shah and Andrew J. Vickers
   Year Published: 2010
   Citation: Pfister, D.G., et al.(2010). Acupuncture for pain and dysfunction after neck dissection: results of a randomized controlled trial. *Journal of Clinical Oncology* 28(15): 2565-70.
   Link to full text: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881730/

Objectives: To determine whether acupuncture reduces pain and dysfunction in patients with cancer with a history of neck dissection. The secondary objective is to determine whether acupuncture relieves dry mouth in this population.

Data sources: Patients and methods at a tertiary cancer center with chronic pain or dysfunction attributed to neck dissection were randomly assigned to weekly acupuncture versus usual care (eg, physical therapy, analgesia, and/or anti-inflammatory drugs, per patient preference or physician recommendation) for 4 weeks.

Review methods: The Constant-Murley score, a composite measure of pain, function, and activities of daily living, was the primary outcome measure. Xerostomia, a secondary end point, was assessed using Xerostomia Inventory.

Results: Fifty-eight evaluable patients were accrued and randomly assigned from 2004 to 2007. Constant-Murley scores improved more in the acupuncture group. Acupuncture produced greater improvement in reported xerostomia.

Conclusions: Significant reductions in pain, dysfunction, and xerostomia were observed in patients receiving acupuncture versus usual care. Although further study is needed, these data support the potential role of acupuncture in addressing post-neck dissection pain and dysfunction, as well as xerostomia.

III. Osteoarthritis

The following synopsis was compiled and organized by Yumiko Freeman, Tara Gregory, and Stephanie Lau in July of 2012 by. At the time they were both Masters students enrolled in the Oregon College of Oriental Medicine.

Please also refer to the first meta analysis presented in this packet, Vickers 2012, to support the effectiveness of acupuncture to address osteoarthritis.

For more information, please see attachment: *Acupuncture for the Treatment of Osteoarthritis*, prepared by Ryan Milley in 2009 for the Society of Acupuncture Research.

ACUPUNCTURE for OSTEOARTHRITIS- RESEARCH AND COMMENTARY

Compiled and Organized by: Yumiko Freeman, Tara Gregory, and Stephanie Lau

The attached research articles illustrate the effectiveness of acupuncture in both reducing pain and increasing function in patients suffering from Osteoarthritis. The research articles include several meta-analysis of clinical studies, an overview of a Cochrane review, and a guideline from the Osteoarthritis Research Society International. The studies demonstrated that acupuncture provided both short-term and long-term pain relief and an increase in function as measured by the use of the Western Ontario and McMaster University Osteoarthritis Index (WOMAC). The clinically relevant results found in the included research studies illustrate that acupuncture is an effective and safe therapy for the relief of Osteoarthritic pain and decreased mobility, either in addition to routine care or for patients concerned about the side effects of standard pharmaceutical intervention.

Title: OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines
Author: Zhang, W., Moskowitz, R., Nuki, G., Abramson, S., Altman, R., Arden, N., et al.
Year Published: 2008
Source: Osteoarthritis Research Society Internaitonal
Type: Guideline based on Systemic Reviews of RCT and meta-analysis
Summary of Article Findings: Guidelines based on sytemic review of research and international experts recommended a combination of non-pharmacological and pharmacological modalities for the optimal treatment of OA of the hip and knee, which included the use of acupuncture.
Link to Full Text:
http://www.oarsi.org/pdfs/oarsi_recommendations_for_management_of_hip_and_knee_oa.pdf

Title: OARSI recommendations for the management of hip and knee osteoarthritis Part III: changes in evidence following systematic cumulative update of research published through January 2009
Authors: W. Zhang*, G. Nuki, R.W. Moskowitz, S. Abramson, R.D. Altman, N.K. Arden, S. Bierma-Zeinstra, K.D. Brandt, P. Croft, M. Doherty, M. Dougados, M. Hochberg, D.J. Hunter, K. Kwoh, L.S. Lohmander, P. Tugwell
Source: Osteoarthritis Research Society International
Link to full Text: http://www.oarsi.org/pdfs/part_III_changes_in_evidence2010.pdf
Acupuncture synopsis, p. 479: Acupuncture
Nine SRs of the use of acupuncture for the treatment of OA published between 2006 and 2009[16,22–29] have confirmed that this non-pharmacological modality of treatment does have some effi- cacy for relief of pain. The latest MA included results from 11 RCTs[23]. Acupuncture was compared with sham acupuncture, usual care or waiting list controls. Overall, acupuncture was superior to controls with a pooled ES of 0.58 (0.38, 0.78) for pain relief. However, the ES was lower in blinded trials with sham acupuncture controls (ES 1⁄4 0.35, 95% CI 0.15, 0.55). The ES for relief of pain also diminished with time and was 0.13 (0.01, 0.24) 6 months after treatment[23]. Similar findings were observed for improvement in function (Table I). The cost per QALY of acupuncture in comparisons with sham acupuncture was about $30,519[30] (Table V).

Title: Acupuncture for Improving Chronic Back Pain, Osteoarthritis and Headache
Author: Sherman, K., and Coeytaux, R.
Year Published: 2009
PMID: 20445762
Source: Center for Health Studies
Type: Review of meta-anaysis and sytemic reviews
Summary of Article Findings: The findings demonstrated that acupuncute was superior to no treatment or usual care and a effective alternative to patients seeking to avoid pharmacological treatment.
Link to Full Text:
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2863344/?tool=pubmed

Title: Acupuncture for Pain: An Overview of Cochrane Reviews
Author: Lee, M., and Ernst, E.
Year Published: 2011
PMID: 21359919
Source: Korea Institute of Oriental Medicine

Type: Review of Cochrane Database of Systemic Reviews
Summary of Article Findings: Acupuncture was demostrated to be effective in treating pain associated with peripheral joint osteoarthritis.
Link to Abstract: http://www.ncbi.nlm.nih.gov/pubmed/21359919
Please contact Ben Marx, OCOM Research Dept. if full text is needed: bmarx@ocom.edu

Title: Short-term efficacy of physical interventions in osteoarthritic knee pain. A systematic review and meta-analysis of randomized placebo-controlled trials.
Author: Bjordal, J.M
Year Published: 2007
PMID: 17587446
Source: BioMed Central
Type: Systemic review with meta-analysis
Summary of Article Findings: TENS, EA and LLLT administered with optional doses in an intensive 2-4 week treatment regimen, seem to offer clinically relevant short-term pain relief for OAK.
Link to Abstract: http://www.ncbi.nlm.nih.gov/pubmed/17587446
Link to Full text: http://www.biomedcentral.com/1471-2474/8/51

Title: Acupuncture treatment for chronic knee pain: a systematic review.
Author: White, A.
Year Published: 2009
PMID: 17215263
Source: Rheumatology
Type: Systemic review and meta-analysis of RCTs
Summary of Article Findings: Acupuncture that meets criteria for adequate treatment is superior to sham acupuncture and to no additional intervention in improving pain and function.
Link to Abstract: http://www.ncbi.nlm.nih.gov/pubmed/17215263
Link to Full text: http://rheumatology.oxfordjournals.org/content/46/3/384.long

Title: Acupuncture for peripheral joint osteoarthritis
Author: Manheimer, E.
Year Published: 2010
PMID: 20091527
Source: Cochrane Database Syst Rev.
Type: RCT
Summary of Article Findings: Sham-controlled trials show statistically significant benefits; however, these benefits are small. Waiting list-controlled trials of acupuncture for peripheral joint osteoarthritis suggest statistically significant and clinically relevant benefits.

Link to Abstract: http://www.ncbi.nlm.nih.gov/pubmed/20091527

Link to Full Text:
http://www.thecochranelibrary.com/userfiles/ccoch/file/Acupuncture_ancient_traditions/CD001977.pdf

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ACUPUNCTURE INCLUSION: OREGON'S HEALTH CARE DELIVERY SYSTEMS

Talking Points, Updated 12-10-2012

Prepared by Laura Ocker

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Licensure and Credentialing

- *Acupuncture is a standardized, licensed and regulated health care profession that conducts training in accredited institutions, and provides safe, low cost, and comparatively effective health care services*.[1] – American Association of Acupuncture and Oriental Medicine Position Statement in Support of the Designation of Acupuncture as an Essential Health Benefit, January 2012

- Acupuncturists in Oregon are licensed by the Oregon Medical Board. A Licensed Acupuncturist (LAc) *provides health care using acupuncture and other forms of traditional Oriental Medicine. Acupuncture treats neurological, organic or functional disorders by stimulation of specific points on the surface of the body by insertion of needles. Under Oregon law, the practice of acupuncture also includes traditional and modern techniques of Oriental diagnosis and evaluation; Oriental massage, exercise and related therapeutic methods; use of Oriental herbs, vitamins, minerals, and dietary advice.* [2]

- Credentialing of Licensed Acupuncturists in Oregon – LAcs, like other practitioners applying for hospital staff, participation in a Health Maintenance Organization (HMO), or Independent Practice Association (IPA), complete the State of Oregon Credentialing Application. Established by House Bill 2144 (1999), the Advisory Committee on Physician Credentialing Information (ACPCI) develops the uniform application used by hospitals and health plans to credential and recredential practitioners within the state of Oregon.

- NIH / National Center for Complementary and Alternative Medicine, Licensure of CAM Practitioners: Acupuncture [3]

  States with licensure: 42 states and the District of Columbia

  Education: 3 years or 1,905 hours, including Chinese herbology and clinical practice; some states require training in anatomy, physiology, and pathology.

  Examination: Most states require the NCCAOM written exam, or a state written exam. Some states also require the Practical Examination of Point Location Skills (PEPLS), or a state practical exam.

  Continuing Education: 16 states require some continuing education units (CEUs); average is 15 hours per year.

- The National Certification Commission for Acupuncture and Oriental Medicine - *NCCAOM certification or a passing score on the NCCAOM certification examinations are documentation of competency for licensure as an acupuncturist by 43 states plus the District of Columbia which represents 98% of the states that regulate acupuncture*.[4]

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Evidence and Effectiveness

- The World Health Organization recognizes these *"Diseases, symptoms or conditions for which acupuncture has been proved-through controlled trials-to be an effective treatment: Adverse reactions to radiotherapy and/or chemotherapy, Allergic rhinitis (including hay fever), Biliary colic, Depression (including depressive neurosis and depression following stroke), Dysentery, acute bacillary Dysmenorrhoea, primary Epigastralgia, acute (in peptic ulcer, acute and chronic gastritis, and gastrospasm), Facial pain (including craniomandibular disorders), Headache, Hypertension, essential Hypotension, primary Induction of labour, Knee pain, Leukopenia, Low back pain, Malposition of fetus, correction of Morning sickness, Nausea and vomiting, Neck pain, Pain in dentistry (including dental pain and temporomandibular dysfunction), Periarthritis of shoulder, Postoperative pain, Renal colic, Rheumatoid arthritis, Sciatica, Sprain, Stroke, Tennis elbow."* [5]

- Since 2005 numerous high quality systematic reviews and medical guidelines have been published, indicating that acupuncture may be a safe and effective treatment for a variety of conditions. The body of evidence is growing and includes research to support acupuncture and Chinese medicine as promising practices for chronic pain [6], migraine and tension headaches, [7], [8], tempomandibular joint disorder, [9] osteoarthritis, [10] low back pain, [11] [12], maternity care (nausea with pregnancy [13],[14],[15], breech presentation [16],[17],[18], back and pelvic pain of pregnancy [19],[20]), post-operative nausea [21], shoulder pain [22] and depression [23] following stroke, irritable bowel syndrome [24], and anxiety, [25] among other conditions.

- In the past two years, Oregon's Health Evidence Review Commission has restored acupuncture to several lines on the Prioritized List in acknowledgement of the quality of research supporting the practice.

- In September 2012, a meta-analysis was published demonstrating clear efficacy of acupuncture for a variety of chronic pain conditions. [26] The National Institutes of Health is calling it the most rigorous evidence to date that acupuncture may be helpful for chronic pain.

  A recent NCCAM-funded study, employing individual patient data meta-analyses and published in the Archives of Internal Medicine, provides the most rigorous evidence to date that acupuncture may be helpful for chronic pain. [27]

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Addressing the Chronic Pain Problem

- According to a report published by the Institute of Medicine in June 2011: [28]

  Chronic pain affects at least 116 million American adults – more than the total affected by heart disease, cancer, and diabetes combined.

  Pain costs the nation up to $635 billion each year in medical treatment and lost productivity.

- According to a Centers for Disease Control and Prevention Policy Impact Statement, published in 2011: [29]

  Drug overdose death rates in the United States have more than tripled since 1990 and have never been higher.

  In 2008, more than 36,000 people died from drug overdoses, and most of these deaths were caused by prescription drugs.

  The misuse and abuse of prescription painkillers was responsible for more than 475,000 emergency department visits in 2009, a number that nearly doubled in just five years.

  People on Medicaid are prescribed painkillers at twice the rate of non-Medicaid patients and are at six times the risk of prescription painkiller overdose.

- According to the Oregon CD Summary, Vol.58, No.20 (9/29/2009), Opiod-related Poisoning Deaths in Oregon:

  The current epidemic of deaths due to prescription drugs is far greater in magnitude than the crack cocaine or heroine mortality epidemics in the past.

- ***There is a high potential for acupuncture and chiropractic care to provide safe and effective treatment for chronic pain. … Americans seek CAM treatments far more often for chronic musculoskeletal pain (CMP) than for any other condition. Among CAM treatments for CMP, acupuncture and chiropractic care are among those with the highest acceptance by physician groups and the best evidence to support their use. Further, recent alarming increases in delivery of opioid treatment and surgical interventions for chronic pain - despite their high costs, potential adverse effects, and modest efficacy - suggests the need to evaluate real world outcomes associated with promising non-pharmacological/non-surgical CAM treatments for CMP, which are often well accepted by patients and increasingly used in the community*. [30] – From a study proposal published in 2011 by researchers from the Kaiser Permanente Center for Health Research in Portland, Oregon.**

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Expanding Access to Acupuncture / CAM and Consumer Preferences

- According to a recent CAM Survey: "More Hospitals Offering Complementary and Alternative Medicine Services," September 7, 2011, American Hospital Association, Samueli Institute: [31]

  42% of respondent hospitals indicated they offer one or more CAM therapies, up from 37 % in 2007.

  85% of responding hospitals indicated patient demand as the primary rationale in offering CAM services and 70% of survey respondents stated clinical effectiveness as their top concern.

- According to another recent CAM Survey from the Health Services Research: HSR-10-0587: "Personal Use of Complementary and Alternative Medicine by U.S. Healthcare Workers," Aug / Sep 2011: [32]

  Principal Findings: Healthcare workers are more likely than the general population to use CAM.

  Among healthcare workers, healthcare providers are more likely to use CAM than other occupations.

- A 2012 systematic review researching the acceptance of CAM found that "the present data demonstrate an increase of CAM usage from 1990 through 2006 in all countries investigated." According to the review, the ailments most often associated with CAM utilization included back pain, depression, insomnia, headache, and digestive illnesses. [33]

- A report conducted by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) showed that in 2010 almost 4 out of 10 adults had used CAM therapy in the last 12 months. And that between 2002 and 2007 increased use was seen among adults for acupuncture. [34]

- According to an article published in The *New York Times* on December 5, 2012, four states have included acupuncture as an Essential Health Benefit, and two others are likely to include acupuncture.

  Most of the roughly two dozen states that have chosen their essential benefits — services that insurance will have to cover under the law — have decided to include chiropractic care in their package. Four states — California, Maryland, New Mexico and Washington — included acupuncture for treating pain, nausea and other ailments. It is also likely to be an essential benefit in Alaska and Nevada, according to the Department of Health and Human Services. [35]

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ACUPUNCTURE INCLUSION: OREGON'S HEALTH CARE DELIVERY SYSTEMS

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Implementation and Containing Costs

- Offering open access to acupuncture on-site through Oregon's CCOs may play a significant role in reducing unnecessary emergency department visits, particularly for clients suffering from chronic pain, anxiety, and addictions

- A study published in 2011 by researchers from the Kaiser Permanente Northwest Center for Health Research suggests that group acupuncture clinics within conventional managed care networks may be a feasible model of care and an effective strategy to address chronic pain. The study found that "chronic pain patients who received acupuncture at KPNW were generally satisfied with the care received and reported improvements in quality of life and pain control." [36]

- Two recent studies, published in 2010 and 2012, respectively, compared health care expenditures for CAM and non-cam users. CAM users appeared to accrue lower health expenditures overall than non-cam users, even when adjustments were made for socioeconomic factors and health status.

  2010 study comparing health care expenditures in Washington state:

  The conclusion of this analysis is that in a large group of insured individuals, patients who use CAM providers for some of their care have lower expenditures as a group than a matched group of patients who do not use CAM, and the difference in expenditures is related in large part to less inpatient care and less use of high-tech imaging. [37]

  2012 study examining expenditures for neck and back pain:

  We observed significantly lower overall and spine specific medical costs among CAM users compared with non-CAM users in a regression model adjusted for patient characteristics, diagnosis, socioeconomic factors, and health status. The lower total costs among CAM users was primarily attributable to their lower expenditures for inpatient services. After excluding inpatient expenditures, there was no difference in spine-specific or overall medical expenditures between CAM and non-CAM users. [38]

- The Kaiser Family Foundation 2004 annual survey of employer-sponsored health plans found that 50% of larger firms (200 or more employees) offered coverage for acupuncture. [39]

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Why Include Acupuncture in Oregon's Health Care Delivery Systems

Essential Health Benefits, Oregon Health Plan, Public Employees Benefit Board (PEBB), Insurance Exchange, Coordinated Care Organizations – there is a place for acupuncture under each of these systems, although the rollout may appear different for each system.

Oregonians value acupuncture and perceive it as a practice that indicates high quality of care. Chinese medicine is a preventative medicine with extraordinary efficacy in promoting health and preventing disease.

Maintaining Licensed Acupuncturists on staff of Oregon's CCOs is one way to support the mission and intent of the CCOs:

1. *A network of all types of health care providers (physical health care, addictions and mental health care and sometimes dental care providers) who have agreed to work together in their communities to serve people who receive health care coverage under the Oregon Health Plan (Medicaid).*

2. *CCOs are focused on prevention and helping people manage chronic conditions. This helps reduce unnecessary emergency room visits and gives people support to be healthy. CCOs focus on better coordination of care to limit unnecessary tests and medications.*

3. *CCOs support a patient-centered model of care.*

Providing acupuncture on site at CCOs may significantly improve health outcomes and play an important role in reducing unnecessary emergency department visits.

> ***With many high-risk, vulnerable individuals seeking chronic opiate therapy for pain management, it is imperative that we offer services that effectively treat pain and anxiety, while minimizing the use of high-risk medications. Acupuncture has been invaluable to us in this regard, and has helped to shape our small, homeless clinic into a model practice for skillful and effective pain management. In our community, one of the top drivers of ED utilization is the triad of chronic pain, substance abuse, and trauma history. The availability of acupuncture services at Central City Concern has significantly impacted our ability to effectively treat this polytrauma triad.*** –
>
> **Rachel Solotaroff, MD, MS, Medical Director, Central City Concern, November 28, 2012** [40]

ACUPUNCTURE INCLUSION: OREGON'S HEALTH CARE DELIVERY SYSTEMS

Talking Points, Updated 12-10-2012

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ONLINE FIRST

Acupuncture for Chronic Pain

Individual Patient Data Meta-analysis

Andrew J. Vickers, DPhil; Angel M. Cronin, MS; Alexandra C. Maschino, BS; George Lewith, MD; Hugh MacPherson, PhD; Nadine E. Foster, DPhil; Karen J. Sherman, PhD; Claudia M. Witt, MD; Klaus Linde, MD; for the Acupuncture Trialists' Collaboration

Background: Although acupuncture is widely used for chronic pain, there remains considerable controversy as to its value. We aimed to determine the effect size of acupuncture for 4 chronic pain conditions: back and neck pain, osteoarthritis, chronic headache, and shoulder pain.

Methods: We conducted a systematic review to identify randomized controlled trials (RCTs) of acupuncture for chronic pain in which allocation concealment was determined unambiguously to be adequate. Individual patient data meta-analyses were conducted using data from 29 of 31 eligible RCTs, with a total of 17 922 patients analyzed.

Results: In the primary analysis, including all eligible RCTs, acupuncture was superior to both sham and no-acupuncture control for each pain condition ($P<.001$ for all comparisons). After exclusion of an outlying set of RCTs that strongly favored acupuncture, the effect sizes were similar across pain conditions. Patients receiving acupuncture had less pain, with scores that were 0.23 (95% CI, 0.13-0.33), 0.16 (95% CI, 0.07-0.25), and 0.15 (95% CI, 0.07-0.24) SDs lower than sham controls for back and neck pain, osteoarthritis, and chronic headache, respectively; the effect sizes in comparison to no-acupuncture controls were 0.55 (95% CI, 0.51-0.58), 0.57 (95% CI, 0.50-0.64), and 0.42 (95% CI, 0.37-0.46) SDs. These results were robust to a variety of sensitivity analyses, including those related to publication bias.

Conclusions: Acupuncture is effective for the treatment of chronic pain and is therefore a reasonable referral option. Significant differences between true and sham acupuncture indicate that acupuncture is more than a placebo. However, these differences are relatively modest, suggesting that factors in addition to the specific effects of needling are important contributors to the therapeutic effects of acupuncture.

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ACUPUNCTURE IS THE INSERTION and stimulation of needles at specific points on the body to facilitate recovery of health. Although initially developed as part of traditional Chinese medicine, some contemporary acupuncturists, particularly those with medical qualifications, understand acupuncture in physiologic terms, without reference to premodern concepts.[1]

An estimated 3 million American adults receive acupuncture treatment each year,[2] and chronic pain is the most common presentation.[3] Acupuncture is known to have physiologic effects relevant to analgesia,[4,5] but there is no accepted mechanism by which it could have persisting effects on chronic pain. This lack of biological plausibility, and its provenance in theories lying outside of biomedicine, makes acupuncture a highly controversial therapy.

A large number of randomized controlled trials (RCTs) of acupuncture for chronic pain have been conducted. Most have been of low methodologic quality, and, accordingly, meta-analyses based on these RCTs are of questionable interpretability and value.[6] Herein, we present an individual patient data meta-analysis of RCTs of acupuncture for chronic pain, in which only high-quality RCTs were eligible for inclusion. Individual patient data meta-analysis are superior to the use of summary data in meta-analysis because they enhance data quality, enable different forms of outcome to be combined, and allow use of statistical techniques of increased precision.

See also
Invited Commentary

Author Affiliations are listed at the end of this article.
Group Information: The members of the Acupuncture Trialists' Collaboration are listed at the end of this article.

The National Collaborating Centre

for Chronic Conditions

Funded to produce guidelines for the NHS by NICE

OSTEOARTHRITIS

National clinical guideline for care and management in adults

Published by

Royal College of Physicians

Setting higher medical standards

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The National Collaborating Centre for Chronic Conditions

The National Collaborating Centre for Chronic Conditions (NCC-CC) is a collaborative, multiprofessional centre undertaking commissions to develop clinical guidance for the NHS in England and Wales. The NCC-CC was established in 2001. It is an independent body, housed within the Clinical Standards Department at the Royal College of Physicians of London. The NCC-CC is funded by the National Institute for Health and Clinical Excellence (NICE) to undertake commissions for national clinical guidelines on an annual rolling programme.

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Preface

Osteoarthritis is the most common disease of the joints, and one of the most widespread of all chronic diseases. Frequently described as 'wear and tear', its prevalence increases steadily with age and by retirement age the associated radiological changes can be observed in over half the population. Symptoms can vary from minimal to severe pain and stiffness, but overall the disease is responsible for considerable morbidity and is a common reason for GP consultation. Unfortunately, it is also difficult to treat and inevitably a wide range of potential therapies have been advocated, both by conventional and complementary practitioners, and not necessarily with strong supporting evidence.

The high prevalence of osteoarthritis, the numerous forms of potential treatment and the uncertainty around these all make the disorder an excellent topic for a clinical guideline. The lack of evidence in some areas is a less favourable feature, and although this has presented something of a challenge, the GDG has risen to this admirably. As with all NICE guidelines, an exhaustive literature search has been performed and the papers identified in this process have been rigorously assessed. Where it is possible to make recommendations based on good evidence, the GDG have done so; where evidence is not available or is weak, they have either made recommendations on the basis of strong clinical consensus, or have advocated appropriate research.

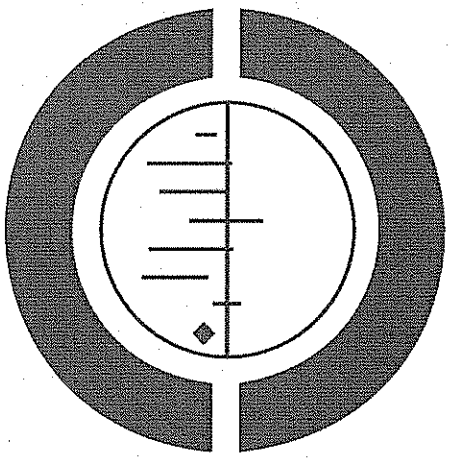
The guideline contains a number of recommendations which are not currently routine practice for many clinicians. While the place of paracetamol in early pain management is confirmed, the guideline also suggests early consideration of topical non-steroidal anti-inflammatory drugs (NSAIDs) for knee and hand arthritis, and suggests that wherever systemic NSAIDs or cyclooxygenase-2 (COX-2) inhibitors are used, they should be coprescribed with cover from a proton pump inhibitor (PPI). This latter recommendation will surprise many, but with PPIs now coming off patent, it is clearly backed up by our health economic analysis. The positive role of exercise is emphasised in contrast to the natural inclination some might have to rest when a joint is affected by osteoarthritis. The GDG has also not shied away from negative recommendations. They suggest that arthroscopic lavage and debridement is not suitable therapy for osteoarthritis except in clear instances where this is associated with mechanical locking; and they do not recommend the use of intra-articular hyaluronans. Elsewhere, there is only restricted support for the use of acupuncture.

The process of producing a guideline is rarely straightforward and there have been occasional difficulties along the way. The GDG have navigated all these with good humour and a consistent desire to evaluate all evidence as thoroughly as they possibly could in order to improve the management of this difficult condition. We at the NCC-CC are grateful to them for all of their work. The guideline is a tribute to their efforts and we hope and expect that it can be used both to practical benefit and to raise the profile of this sometimes neglected condition.

Dr Bernard Higgins MD FRCP
Director, National Collaborating Centre for Chronic Conditions

Acupuncture for peripheral joint osteoarthritis (Review)

Manheimer E, Cheng K, Linde K, Lao L, Yoo J, Wieland S, van der Windt DAWM, Berman BM, Bouter LM



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[Intervention Review]

Acupuncture for peripheral joint osteoarthritis

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ABSTRACT

Background

Peripheral joint osteoarthritis is a major cause of pain and functional limitation. Few treatments are safe and effective.

Objectives

To assess the effects of acupuncture for treating peripheral joint osteoarthritis.

Search strategy

We searched the Cochrane Central Register of Controlled Trials (*The Cochrane Library* 2008, Issue 1), MEDLINE, and EMBASE (both through December 2007), and scanned reference lists of articles.

Selection criteria

Randomized controlled trials (RCTs) comparing needle acupuncture with a sham, another active treatment, or a waiting list control group in people with osteoarthritis of the knee, hip, or hand.

Data collection and analysis

Two authors independently assessed trial quality and extracted data. We contacted study authors for additional information. We calculated standardized mean differences using the differences in improvements between groups.

Main results

Sixteen trials involving 3498 people were included. Twelve of the RCTs included only people with OA of the knee, 3 only OA of the hip, and 1 a mix of people with OA of the hip and/or knee. In comparison with a sham control, acupuncture showed statistically significant, short-term improvements in osteoarthritis pain (standardized mean difference -0.28, 95% confidence interval -0.45 to -0.11; 0.9 point greater improvement than sham on 20 point scale; absolute percent change 4.59%; relative percent change 10.32%;

REVIEW ARTICLE

Acupuncture for Chronic Pain: Is Acupuncture More than an Effective Placebo? A Systematic Review of Pooled Data from Meta-analyses

Ann Hopton, MSc; Hugh MacPherson, PhD
Department of Health Sciences, University of York, York, U.K.

■ **Abstract**

Objectives: There is controversy as to whether or not acupuncture is more effective than placebo. To help clarify this debate, we synthesized the evidence gathered from systematic reviews on the pooled data of high-quality randomized controlled trials comparing acupuncture to sham acupuncture for chronic pain.

Method: Systematic reviews of acupuncture for the most commonly occurring forms of chronic pain (back, knee, and head) published between 2003 and 2008 were sourced from Ovid databases: Medline, Allied and Complementary Medicine database, Cochrane Library and Web of Science during December 2008. Eight systematic reviews with meta-analyses of pooled data were eligible for inclusion. Data were extracted for short- and longer-term outcomes for the most commonly occurring forms of pain. Two independent reviewers assessed methodological quality.

Results: For short-term outcomes, acupuncture showed significant superiority over sham for back pain, knee pain, and headache. For longer-term outcomes (6 to12 months), acupuncture was significantly more effective for knee pain and tension-type headache but inconsistent for back pain (one positive and one inconclusive). In general, effect sizes (standardized mean differences) were found to be relatively small.

Discussion: The accumulating evidence from recent reviews suggests that acupuncture is more than a placebo for commonly occurring chronic pain conditions. If this conclusion is correct, then we ask the question: is it now time to shift research priorities away from asking placebo-related questions and shift toward asking more practical questions about whether the overall benefit is clinically meaningful and cost-effective? ■

Key Words: acupuncture, placebo, acupuncture analgesia, systematic review, back pain, knee pain, headache, chronic pain

INTRODUCTION

Chronic pain of moderate to severe intensity is a widespread problem that affects the every day activities of one in four adult Americans,[1] and one in five adults across Europe.[2] The majority of chronic pain sufferers in the U.S.A. and Europe have reported inadequate pain control and one-third worry about addiction to pain medication.[2,3] In the U.K., 81% of family practitioners believe that a significant number of their patients receive

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Advance Access publication 27 August 2006
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Review

Acupuncture for peripheral joint osteoarthritis

A systematic review and meta-analysis

Y. D. Kwon[1,2], M. H. Pittler[1] and E. Ernst[1]

***Objective*. To evaluate the evidence for the effectiveness of acupuncture in peripheral joint osteoarthritis (OA).**
***Methods*. Systematic searches were conducted on Medline, Embase, AMED, Cochrane Library, CINAHL, British Nursing Index, PsychINFO and CAMPAIN until July 2005. Hand-searches included conference proceedings and our own files. There were no restrictions regarding the language of publication. All randomized controlled trials (RCTs) of acupuncture for patients with peripheral joint OA were considered for inclusion. Trials assessing needle acupuncture with or without electrical stimulation were considered if sham- or placebo-controlled or controlled against a comparator intervention. Trials testing other forms of acupuncture were excluded. Methodological quality was assessed and, where possible, meta-analyses were performed.**
***Results*. Thirty-one possibly relevant studies were identified and 18 RCTs were included. Ten trials tested manual acupuncture and eight trials tested electro-acupuncture. Overall, ten studies demonstrated greater pain reduction in acupuncture groups compared with controls. The meta-analysis of homogeneous data showed a significant effect of manual acupuncture compared with sham acupuncture (standardized mean difference 0.24, 95% confidence interval 0.01–0.47, $P = 0.04$, $n = 329$), which is supported by data for knee OA. The extent of heterogeneity in trials of electro-acupuncture prevented a meaningful meta-analysis.**
***Conclusions*. Sham-controlled RCTs suggest specific effects of acupuncture for pain control in patients with peripheral joint OA. Considering its favourable safety profile acupuncture seems an option worthy of consideration particularly for knee OA. Further studies are required particularly for manual or electro-acupuncture in hip OA.**

KEY WORDS: Acupuncture, Osteoarthritis, Randomized controlled trial, Systematic review.

Introduction

Osteoarthritis (OA) is the most common form of arthritis, and the most common reason for total hip and total knee replacement [1]. The underlying disease processes of OA involve cartilage degeneration, proliferation and remodelling of subchondral bone structure. Weight-bearing peripheral and axial joints are most often affected [2]. OA is associated with symptoms of pain and functional disability. Physical disability arising from pain and loss of functional capacity reduces the quality of life and increases the risk of further morbidity and mortality [3]. Among adults aged ≥30 yrs, symptomatic knee OA occurs in ~6% and symptomatic hip OA in about 3% [1]. Before the age of 50 yrs, the prevalence of OA in most joints is higher in men than in women, whereas in later life women are more often affected than men in hands, feet and knees [4].

The treatment of OA is largely symptomatic and includes analgesics, NSAIDS, glucosamine, topical analgesics such as capsaicin cream as well as exercise, behavioural interventions and surgical treatment [5]. Most drug treatments are associated with well-documented risks such as gastrointestinal irritation and bleeding, renal and hepatic toxicity, as well as an increased risk of hypertension. Some of these adverse events are most prominent in the elderly—the very group most commonly affected by OA [6].

Non-pharmacological treatments such as acupuncture are therefore attractive. Acupuncture is often used for OA and chronic pain relief [2, 7]. In the US, over 2 million people use acupuncture annually [8]. To evaluate the evidence for the effectiveness of acupuncture in peripheral joint OA, we conducted a systematic review and meta-analysis of randomized controlled trials (RCTs).

Methods

Data sources

Searches were performed in July 2005 using Medline, Embase, AMED, CINAHL, British Nursing Index, PsychINFO, CAMPAIN and Cochrane Library. Search terms used were OA, degenerative arthritis, osteoarthrosis, joint pain, knee pain, hip pain, arthritis, acupuncture, ear acupuncture and electro-acupuncture. In addition, our own files were manually searched and authors were contacted. Original articles were obtained, and all reference lists were scanned for further relevant articles.

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SPECIAL ARTICLE

American College of Rheumatology 2012 Recommendations for the Use of Nonpharmacologic and Pharmacologic Therapies in Osteoarthritis of the Hand, Hip, and Knee

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Guidelines and recommendations developed and/or endorsed by the American College of Rheumatology (ACR) are intended to provide guidance for particular patterns of practice and not to dictate the care of a particular patient. The ACR considers adherence to these guidelines and recommendations to be voluntary, with the ultimate determination regarding their application to be made by the physician in light of each patient's individual circumstances. Guidelines and recommendations are intended to promote beneficial or desirable outcomes but cannot guarantee any specific outcome. Guidelines and recommendations developed or endorsed by the ACR are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice.

The American College of Rheumatology is an independent, professional, medical and scientific society which does not guarantee, warrant, or endorse any commercial product or service.

Objective. **To update the American College of Rheumatology (ACR) 2000 recommendations for hip and knee osteoarthritis (OA) and develop new recommendations for hand OA.**

Methods. **A list of pharmacologic and nonpharmacologic modalities commonly used to manage knee, hip, and hand OA as well as clinical scenarios representing patients with symptomatic hand, hip, and knee OA were generated. Systematic evidence-based literature reviews were conducted by a working group at the Institute of Population Health, University of Ottawa, and updated by ACR staff to include additions to bibliographic databases through December 31, 2010. The Grading of Recommendations Assessment, Development and Evaluation approach, a formal process to rate scientific evidence and to develop recommendations that are as evidence based as possible, was used by a Technical Expert Panel comprised of various stakeholders to formulate the recommendations for the use of nonpharmacologic and pharmacologic modalities for OA of the hand, hip, and knee.**

Results. **Both "strong" and "conditional" recommendations were made for OA management. Modalities conditionally recommended for the management of hand OA include instruction in joint protection techniques, provision of assistive devices, use of thermal modalities and trapeziometacarpal joint splints, and use of oral and topical nonsteroidal antiinflammatory drugs (NSAIDs), tramadol, and topical capsaicin. Nonpharmacologic modalities strongly recommended for the management of knee OA were aerobic, aquatic, and/or resistance exercises as well as weight loss for overweight patients. Nonpharmacologic modalities conditionally recommended for knee OA included medial wedge insoles for valgus knee OA, subtalar strapped lateral insoles for varus knee OA, medially directed patellar taping, manual therapy, walking aids, thermal agents, tai chi, self-management programs, and psychosocial interventions. Pharmacologic modalities conditionally recommended for the initial management of patients with knee OA included acetaminophen, oral and topical NSAIDs, tramadol, and intraarticular corticosteroid injections; intraarticular hyaluronate injections, duloxetine, and opioids were conditionally recommended in patients who had an inadequate response to initial therapy. Opioid analgesics were strongly recommended in patients who were either not willing to undergo or had contraindications for total joint arthroplasty after having failed medical therapy. Recommendations for hip OA were similar to those for the management of knee OA.**

Conclusion. **These recommendations are based on the consensus judgment of clinical experts from a wide range of disciplines, informed by available evidence, balancing the benefits and harms of both nonpharmacologic and pharmacologic modalities, and incorporating their preferences and values. It is hoped that these recommendations will be utilized by health care providers involved in the management of patients with OA.**

INTRODUCTION

Many patients with a clinical diagnosis of osteoarthritis (OA) are treated with a combination of nonpharmacologic and pharmacologic modalities (1). The American College of Rheumatology (ACR) last published recommendations for the management of hip and knee OA in 2000 (2), with

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Clinical Policy Bulletin:
Acupuncture
Number: 0135

Policy

Note: Most Aetna plans limit coverage of acupuncture to when it is used in a lieu of other anesthesia for a surgical or dental procedure covered under the health benefits plan, and the health care provider administering it is a legally qualified physician practicing within the scope of his/her license. Other plans may extend coverage of acupuncture for medically necessary indications, but only when administered by a health care provider who is a legally qualified physician practicing within the scope of his/her license. Please check benefit plan descriptions for details.

Aetna considers needle acupuncture (manual or electroacupuncture) medically necessary for any of the following indications:

- Chronic low back pain. (Maintenance treatment, where the patient's symptoms are neither regressing or improving, is considered not medically necessary. If no clinical benefit is appreciated after 4 weeks, then the treatment plan should be reevaluated); *or*
- Migraine headache; *or*
- Nausea of pregnancy; *or*
- Pain from osteoarthritis of the knee or hip (adjunctive therapy; if no clinical benefit is appreciated after 4 weeks, then the treatment plan should be reevaluated); *or*
- Post-operative and chemotherapy-induced nausea and vomiting; *or*
- Post-operative dental pain; *or*
- Temporomandibular disorders (TMD)

Aetna considers acupuncture experimental and investigational for all other indications, including but not limited to any of the following conditions, because there is inadequate scientific research assessing the efficacy of acupuncture compared with placebo, sham acupuncture or other modalities of treatment in these conditions:

Acute low back pain Addiction AIDS	Neck pain/cervical spondylosis Obesity

Policy History
Last Review: 04/27/2012
Effective: 07/19/1996
Next Review: 02/14/2013
Review History
Definitions
Additional Information
Clinical Policy Bulletin Notes

State Information
Texas

Cigna Medical Coverage Policy

Effective Date **3/15/2012**
Next Review Date **3/15/2013**
Coverage Policy Number **0024**

Subject **Acupuncture**

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Botulinum Therapy
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Plantar Fasciitis Treatments
Temporomandibular Joint (TMJ) Disorder Surgery

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Coverage Policy

Acupuncture is specifically excluded under many benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Some plans that provide coverage for acupuncture include a maximum allowable benefit for duration of treatment or number of visits. When the maximum allowable benefit is exhausted, coverage will no longer be provided even if the medical necessity criteria described below are met.

If coverage is available for acupuncture, the following conditions of coverage apply.

Cigna covers acupuncture as medically necessary for any of the following indications:

- nausea and vomiting associated with pregnancy
- nausea and vomiting associated with chemotherapy
- postoperative nausea and vomiting
- postoperative dental pain

Acupuncture for Chronic Neck Pain

Question: should acupuncture be added for treatment of chronic neck pain?

Question source: Laura E. Ocker, LAc, President, OAAOM

Issue: Acupuncture is currently on the Prioritized List for treatment of various conditions, including drug addiction, HIV, depression following stroke, several pregnancy related conditions, low back pain, migraine and tension headaches. There is a guideline limiting use of acupuncture for several of these conditions. The Oregon Association of Acupuncture and Oriental Medicine (OAAOM) and the Oregon College of Oriental Medicine (OCOM) are jointly requesting that acupuncture be considered for pairing with several chronic pain conditions, including neck pain, osteoarthritis, and shoulder pain.

Current Prioritized List placement:
723.1 (Cervicalgia)
723.8 (Other syndromes affecting cervical region)
723.9 (Unspecified musculoskeletal disorders and symptoms referable to neck)
847.0 (Sprain of neck)

All located on line 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT

Evidence

1) **Vickers 2012**; patient level meta-analysis of high quality RCTs
    a. N=5 studies for chronic neck pain
    b. Acupuncture was superior to both sham and no acupuncture control for each pain condition (*P*<.001 for all comparisons).
    c. Back and neck pain: pain reduced 0.23 (95% CI, 0.13-0.33) vs sham control and 0.55 (95% CI, 0.51-0.58) vs no acupuncture control
2) **Trinh 2010**, Cochrane systematic review of acupuncture for treatment of chronic neck pain (>90 days)
    a. N=10 trials (most studies were very small—fewer than 100 patients; range was 13 to 177)
    b. Diagnoses included
        i. Mechanical neck disorders (MND), including whiplash associated disorders
        ii. myofascial neck pain
        iii. degenerative changes (DC)
        iv. Neck disorder with headache
        v. Neck disorders with radicular symptoms

   a. For chronic mechanical neck disorders, there was moderate evidence that acupuncture was more effective for pain relief than some types of sham controls, measured immediately post-treatment. There was moderate evidence that acupuncture was more effective than inactive, sham treatments measured immediately post-treatment and at short-term follow-up (pooled standardized mean difference (SMD) -0.37, 95% confidence interval (CI) -0.61 to -0.12). There was limited evidence that acupuncture was more effective than massage at short-term follow-up. For chronic neck disorders with radicular symptoms, there was moderate evidence that acupuncture was more effective than a wait-list control at short-term follow-up.
   b. **Authors' conclusions** There is moderate evidence that acupuncture relieves pain better than some sham treatments, measured at the end of the treatment. There is moderate evidence that those who received acupuncture reported less pain at short term follow-up than those on a waiting list. There is also moderate evidence that acupuncture is more effective than inactive treatments for relieving pain post-treatment and this is maintained at short-term follow-up.

2) **Hurwitz 2008,** Bone and Joint Taskforce evidence summary for non invasive treatments for neck pain
   a. N=6 trials with sub acute or chronic neck pain
   b. Short term clinical outcomes favored needle acupuncture vs. massage, myofasical trigger point therapy or sham laser acupuncture
   c. No differences seen between acupuncture and massage or manual therapy at 6 months
   d. In one study, general practice patients with neck pain of more than 6 months' duration experienced much greater reductions in neck pain and disability (from baseline to 3-months) when randomized to a 3-month course of up to 15 sessions of needle acupuncture. More than twice as many acupuncture patients improved by 20% or more
   e. For non-whiplash neck pain, the evidence suggests that manual and supervised exercise interventions, low-level laser therapy, and perhaps acupuncture are more effective than no treatment, sham, or alternative interventions; however, none of the active treatments was clearly superior to any other in either the short- or long-term.

Other policies

1) **Aetna 2012**
   a. Does not cover acupuncture for neck pain/whiplash
2) **Cigna 2012**
   a. Covers acupuncture for neck pain

Summary

Acupuncture for chronic neck pain appears to be clinically significant short term benefit, but no long term benefit for acupuncture.

Recommendations:

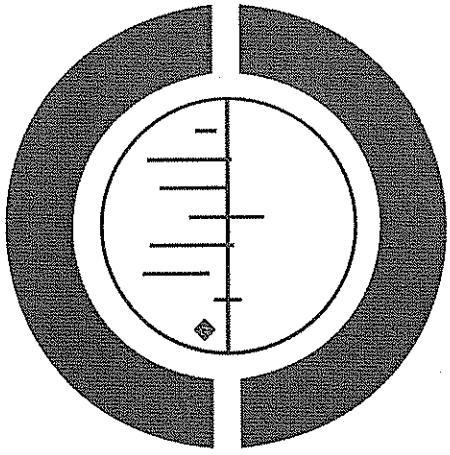
1) Add acupuncture (CPT 97810-4) to line 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT
2) Modify the acupuncture guideline as shown in the separate document titled "Acupuncture Guideline" and excerpted below

Line 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT

Acupuncture pairs on Line 562 ~~only~~ with the low back diagnoses (M47.816, M47.817, M47.896, M47.897, M48.36, M48.37, M51.26, M51.27, M51.36, M51.37, M51.86, M51.87, M54.5, M62.830, S33.5xxA, S33.9xxA, S39.092A, S39.82xA, S39.93xA), when referred, for up to 12 sessions. Acupuncture pairs with chronic (>90 days) neck pain diagnoses (723.1, 723.8, 723.9, 847.0), when referred, for up to 12 sessions

Acupuncture for neck disorders (Review)

Trinh K, Graham N, Gross A, Goldsmith CH, Wang E, Cameron ID, Kay TM, Cervical Overview Group



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[Intervention Review]

Acupuncture for neck disorders

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Editorial group: Cochrane Back Group.
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ABSTRACT

Background

Neck pain is one of the three most frequently reported complaints of the musculoskeletal system. Treatments for neck pain are varied, as are the perceptions of benefits. Acupuncture has been used as an alternative to more traditional treatments for musculoskeletal pain. This review summarizes the most current scientific evidence on the effectiveness of acupuncture for acute, subacute and chronic neck pain.

Objectives

To determine the effects of acupuncture for individuals with neck pain.

Search strategy

We searched CENTRAL (2006, issue 1) and MEDLINE, EMBASE, MANTIS, CINAHL from their beginning to February 2006. We searched reference lists and the acupuncture database TCMLARS in China.

Selection criteria

Any published trial using randomized (RCT) or quasi-randomized (quasi-RCT) assignment to the intervention groups, either in full text or abstract form, were included.

Data collection and analysis

Two reviewers made independent decisions for each step of the review: article inclusion, data abstraction and assessment of trial methodological quality. Study quality was assessed using the Jadad criteria. Consensus was used to resolve disagreements. When clinical heterogeneity was absent, we combined studies using random-effects meta-analysis models.

SPINE Volume 33, Number 4S, pp S123–S152

Treatment of Neck Pain: Noninvasive Interventions

Results of the Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders

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J. David Cassidy, DC, PhD, DrMedSc,‖**§§§ and Scott Haldeman, DC, MD, PhD‖‖‖‖‖****

Study Design. Best evidence synthesis.

Objective. To identify, critically appraise, and synthesize literature from 1980 through 2006 on noninvasive interventions for neck pain and its associated disorders.

Summary of Background Data. No comprehensive systematic literature reviews have been published on interventions for neck pain and its associated disorders in the past decade.

Methods. We systematically searched Medline and screened for relevance literature published from 1980 through 2006 on the use, effectiveness, and safety of noninvasive interventions for neck pain and associated disorders. Consensus decisions were made about the scientific merit of each article; those judged to have adequate internal validity were included in our best evidence synthesis.

Results. Of the 359 invasive and noninvasive intervention articles deemed relevant, 170 (47%) were accepted as scientifically admissible, and 139 of these related to noninvasive interventions (including health care utilization, costs, and safety). For whiplash-associated disorders, there is evidence that educational videos, mobilization, and exercises appear more beneficial than usual care or physical modalities. For other neck pain, the evidence suggests that manual and supervised exercise interventions, low-level laser therapy, and perhaps acupuncture are more effective than no treatment, sham, or alternative interventions; however, none of the active treatments was clearly superior to any other in either the short- or long-term. For both whiplash-associated disorders and other neck pain without radicular symptoms, interventions that focused on regaining function as soon as possible are relatively more effective than interventions that do not have such a focus.

Conclusion. Our best evidence synthesis suggests that therapies involving manual therapy and exercise are more effective than alternative strategies for patients with neck pain; this was also true of therapies which include educational interventions addressing self-efficacy. Future efforts should focus on the study of noninvasive interventions for patients with radicular symptoms and on the design and evaluation of neck pain prevention strategies.

Key words: best evidence synthesis, cervical spine, neck pain, whiplash-associated disorder. **Spine 2008;33: S123–S152**

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The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

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Since publication of the Québec Task Force on whiplash-associated disorders (WAD) best evidence synthesis in 1995,[1] several additional systematic reviews of interventions for whiplash and other types of neck pain have been published. However, no comprehensive reviews have been published on the utilization, safety, effectiveness, and cost effectiveness of noninvasive interventions, for both WAD and for nonspecific neck pain and associated disorders. Instead, the reviews typically focus on a specific type of treatment (*e.g.*, manual therapy) or a specific patient population (*e.g.*, those with WAD). Given the recent explosive growth of the neck pain literature and a lack of synthesis, this is an appropriate time to critically examine the evidence and to offer informed judgment about the current state of knowledge regarding noninvasive interventions for neck pain.

Acupuncture for Hip Osteoarthritis

Question: Should acupuncture be added for treatment of hip osteoarthritis?

Question source: Laura E. Ocker, LAc, President, OAAOM

Issue: Acupuncture is currently on the Prioritized List for treatment of various conditions, including drug addiction, HIV, depression following stroke, several pregnancy related conditions, low back pain, migraine and tension headaches. There is a guideline limiting use of acupuncture for several of these conditions. The Oregon Association of Acupuncture and Oriental Medicine (OAAOM) and the Oregon College of Oriental Medicine (OCOM) are jointly requesting that acupuncture be considered for pairing with several chronic pain conditions, including neck pain, osteoarthritis, and shoulder pain.

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Current Prioritized List placement

715.95 (Osteoarthrosis, unspecified whether generalized or localized, lower leg) is currently on lines 384 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE Treatment ARTHROPLASTY/ RECONSTRUCTION and 489 OSTEOARTHRITIS AND ALLIED DISORDERS Treatment MEDICAL THERAPY, INJECTIONS

Evidence

1) **Vickers 2012**; patient level meta-analysis of high quality RCTs
    a. N=9 studies for osteoarthritis
        i. N=8 for knee pain, N=1 for hip pain
    b. Acupuncture was superior to both sham and no acupuncture control for each pain condition (*P*<.001 for all comparisons).
    c. Osteoarthritis: pain reduced 0.16 (95% CI, 0.07-0.25) vs sham control and 0.57 (95% CI, 0.50-0.64) vs no acupuncture control
2) **NICE 2008,** systematic review of acupuncture for osteoarthritis (knee, hip, thumb)
    a. 1 RCT found for hip osteoarthritis (N=67 patients), no significant difference between acupuncture and sham acupuncture in pain or function or quality of life
    b. 1 RCT with hip or knee osteoarthritis (N=712)
        i. Unable to determine which patients had hip diagnoses
        ii. Mean change in pain 43.7% from 2006 with acupuncture vs 6.2% with no acupuncture, p<0.001
        iii. Mean change in stiffness 31.7% (change from 2006) acupuncture vs. 1.5% no acupuncture, p<0.001
        iv. Improved quality of life measures with acupuncture
    a. The studies which have shown superiority of acupuncture over placebo have shown this only in the short term (6–12 weeks). At 26 weeks there are few

studies, and overall they do not support a benefit over placebo. It therefore seems likely that acupuncture can provide short- to medium-term relief for some people.
   b. Acupuncture of peripheral joints appears safe.
   c. The health economic literature is limited and not based in the UK NHS or similar healthcare systems. The incremental cost-effectiveness ratio for acupuncture is often higher than the threshold of £20–£30K per QALY that is typically quoted as what the NHS can afford. However, there is considerable uncertainty about this estimate because of the limitations in the data. However, electro-acupuncture was consistently above the threshold of cost effectiveness.
   d. Recommended against coverage for electro-acupuncture, but made no recommendation on traditional acupuncture
3) **Manheimer 2010**, Cochrane systematic review of acupuncture for peripheral osteoarthritis
   a. N=16 trials, 3498 patients
      i. N=12 OA of knee
      ii. N=3 OA of hip
      iii. N=1 OA of hip or knee
   b. Using just the 3 trials with hip OA (Fink 2001, Halsam 2001, Stener-Victorin 2004), there was no significant change in pain with acupuncture vs. sham control
   c. **Authors' conclusions** Sham-controlled trials show statistically significant benefits; however, these benefits are small, do not meet our pre-defined thresholds for clinical relevance, and are probably due at least partially to placebo effects from incomplete blinding. Waiting list-controlled trials of acupuncture for peripheral joint osteoarthritis suggest statistically significant and clinically relevant benefits, much of which may be due to expectation or placebo effects.
4) **Moe 2007,** evidence based review
   a. **N=**6 reviews of sufficient high quality
   b. There was moderate-quality evidence that acupuncture and diacerein have no effect on pain and function.

Specialty society recommendations

1) American College of Rheumatology (ACR), (**Hochberg 2012**)
   a. Do not review acupuncture for treatment of hip osteoarthritis

Other policies

1) Aetna 2012
   a. Covers acupuncture for treatment of pain from osteoarthritis of the knee or hip (adjunctive therapy; if no clinical benefit is appreciated after 4 weeks, then the treatment plan should be reevaluated)

2) Cigna 2012
   a. Does not cover acupuncture for hip osteoarthritis

Acupuncture for Hip Osteoarthritis

Summary
Acupuncture for osteoarthritis of the hip has little evidence of effectiveness for reducing pain or increasing function.

Recommendation:

1) Do not add acupuncture as a treatment for osteoarthritis of the hip

CARE IV
Conference Series

Effectiveness of Nonpharmacological and Nonsurgical Interventions for Hip Osteoarthritis: An Umbrella Review of High-Quality Systematic Reviews

Rikke H Moe, Espen A Haavardsholm, Anne Christie, Gro Jamtvedt, Kristin Thuve Dahm, Kåre Birger Hagen

An increasing number of systematic reviews are available regarding nonpharmacological and nonsurgical interventions for hip osteoarthritis (OA). The objectives of this article are to identify high-quality systematic reviews on the effect of nonpharmacological and nonsurgical interventions for hip OA and to summarize available high-quality evidence for these treatment approaches. The authors identified and screened 204 reviews. Two independent reviewers using a previously pilot-tested quality assessment form assessed the full text of 58 reviews. Six reviews were of sufficient high quality and could be included for further analyses. There was moderate-quality evidence that acupuncture and diacerein have no effect on pain and function. There was low-quality evidence that strengthening exercises and avocado/soybean unsaponifiables reduce pain and that diacerein decreases radiographic OA progression. There was insufficient high-quality evidence regarding nonpharmacological and nonsurgical interventions for hip OA, and further primary studies and reviews are needed.

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[Moe RH, Haavardsholm EA, Christie A, et al. Effectiveness of nonpharmacological and nonsurgical interventions for hip osteoarthritis: an umbrella review of high-quality systematic reviews. *Phys Ther.* 2007;87:1716–1727.]

Acupuncture for Shoulder Pain/Bursitis

Question: Should acupuncture be added for treatment of shoulder pain/bursitis?

Question source: Laura E. Ocker, LAc, President, OAAOM

Issue: Acupuncture is currently on the Prioritized List for treatment of various conditions, including drug addiction, HIV, depression following stroke, several pregnancy related conditions, low back pain, migraine and tension headaches. There is a guideline limiting use of acupuncture for several of these conditions. The Oregon Association of Acupuncture and Oriental Medicine (OAAOM) and the Oregon College of Oriental Medicine (OCOM) are jointly requesting that acupuncture be considered for pairing with several chronic pain conditions, including neck pain, osteoarthritis, and shoulder pain.

Current Prioritized List placement

726.0 (Adhesive capsulitis) and 726.1 (rotator cuff syndrome) are on line 443 DISORDERS OF SHOULDER,POTENTIALLY RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT, and 715.21 (osteoarthritis of the shoulder) is on line 489 OSTEOARTHRITIS AND ALLIED DISORDERS.

Acupuncture (CPT 97810-4) is currently on lines 1,5,6,15,68,70,212,400,435,562,563.

Evidence

1) **Vickers 2012**; patient level meta-analysis of high quality RCTs
    a. N=4 studies for shoulder pain (1 rotator cuff tendonitis, 3 general shoulder pain)
    b. Acupuncture was superior to both sham and no acupuncture control for each pain condition (*P*<.001 for all comparisons).
2) **Green 2008**, Cochrane systematic review of acupuncture for treatment of shoulder pain
    a. Diagnosis for inclusion: adhesive capsulitis (frozen shoulder), rotator cuff disease and osteoarthritis
    b. N=9 trials
        i. N=2 rotator cuff disease
            1. There was no significant difference in short-term improvement associated with acupuncture when compared to placebo, but due to small sample sizes this may be explained by Type II error.
            2. Acupuncture was of benefit over placebo in improving the Constant Murley Score (a measure of shoulder function) at four weeks (WMD 17.3 (7.79, 26.81)). However, by four months, the difference between the acupuncture and placebo groups, whilst still

statistically significant, was no longer likely to be clinically significant (WMD 3.53 (0.74, 6.32)).

c. **Authors' conclusions:** Due to a small number of clinical and methodologically diverse trials, little can be concluded from this review. There is little evidence to support or refute the use of acupuncture for shoulder pain although there may be short-term benefit with respect to pain and function. There is a need for further well designed clinical trials.

Specialty society recommendations

1) None found

Other policies

1) Aetna 2012

a. Does not cover acupuncture for neck pain/whiplash or shoulder pain (e.g. bursitis)
b.

2) Cigna 2012

a. Does not cover acupuncture for hip osteoarthritis or shoulder conditions

Summary

Acupuncture may result in short term benefit for shoulder pain; however, evidence is too limited to draw definite conclusions.

Recommendations:

1) Do not add acupuncture as a treatment for pain conditions of the shoulder

[Intervention Review]

Acupuncture for shoulder pain

Sally Green[1], Rachelle Buchbinder[2], Sarah E Hetrick[3]

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ABSTRACT

Background

There are many commonly employed forms of treatment for shoulder disorders. This review of acupuncture is one in a series of reviews of varying interventions for shoulder disorders including adhesive capsulitis (frozen shoulder), rotator cuff disease and osteoarthritis. Acupuncture to treat musculoskeletal pain is being used increasingly to confer an analgesic effect and to date its use in shoulder disorder has not been evaluated in a systematic review.

Objectives

To determine the efficacy and safety of acupuncture in the treatment of adults with shoulder pain.

Search strategy

The Cochrane Controlled Trials Register, MEDLINE, EMBASE and CINAHL were searched from inception to December 2003, and reference lists from relevant trials were reviewed.

Selection criteria

Randomised and quasi-randomised trials, in all languages, of acupuncture compared to placebo or another intervention in adults with shoulder pain. Specific exclusions were duration of shoulder pain less than three weeks, rheumatoid arthritis, polymyalgia rheumatica, cervically referred pain and fracture.

Data collection and analysis

Two reviewers independently extracted trial and outcome data. For continuous outcome measures where the standard deviations were not reported it was either calculated from the raw data or converted from the standard error of the mean. If neither of these was reported, authors were contacted. Where results were reported as median and range, the trial was not included in the meta-analysis, but presented in Additional Tables. Effect sizes were calculated and combined in a pooled analysis if the study end-points population and intervention were homogenous. Results are presented separately for rotator cuff disease, adhesive capsulitis, full thickness rotator cuff tear and mixed diagnoses, and, where possible, combined in meta-analysis to indicate effect of acupuncture across all shoulder disorders.

Acupuncture Guideline

Recommended changes to the Acupuncture guideline:

1) Wording changes to reflect the HERC charge to prioritized conditions and treatments, rather than require coverage of certain services
2) Add limited coverage of knee osteoarthritis
3) Add coverage for neck strain/chronic neck pain conditions

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,212,435,489,562,563

Inclusion of acupuncture (CPT 97810-97814) on the Prioritized List has the following limitations:

Line 1 PREGNANCY

Acupuncture ~~(97810-97814)~~ pairs on Line 1 for the following conditions and codes.

Hyperemesis gravidarum

ICD-9 codes: 643.00, 643.03, 643.10, 643.11, 643.13

Acupuncture is paired with ~~for~~ hyperemesis gravidarum ~~is covered~~ when a diagnosis is made by the maternity care provider and referred for acupuncture treatment for u~~U~~p to 2 sessions of acupressure/acupuncture ~~are covered.~~

Breech presentation

ICD-9 codes: 652.20, 652.23

Acupuncture (and moxibustion) is paired with ~~for~~ breech presentation ~~is covered~~ when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 2 visits.

Back and pelvic pain of pregnancy

ICD-9 codes: 648.70, 648.73

Acupuncture is ~~covered~~ paired with ~~for~~ back and pelvic pain of pregnancy when referred by maternity care provider/primary care provider for up to 12 sessions.

Line 212 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Acupuncture is paired with ~~covered on this line for~~ the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time an limited to 15 total sessions, with documentation of meaningful improvement.

Line 400 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT

Acupuncture ~~(97810-97814)~~ is included on Line 400 only for pairing with disorders of the spine with myelopathy and/or radiculopathy represented by the diagnosis codes M47.26, M47.27, M51.06, M51.07, M51.16, M51.17, M51.26, M51.27, M54.16, M54.17 with referral ~~. Acupuncture for the treatment of these conditions is only covered, when referred,~~ for up to 12 sessions.

Line 435 MIGRAINE HEADACHES

Acupuncture pairs on Line 435 for ICD-9 346, when referred, for up to 12 sessions.

Line 489 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on line 489 for treatment of osteoarthritis of the knee only when the patient has chronic moderate to severe pain and is a candidate for total knee arthroplasty but either is unwilling to undergo the procedure, has comorbid medical conditions, or is taking concomitant medications that lead to a relative or absolute contraindication to surgery or a decision by the surgeon not to recommend the procedure

Alternative:

Acupuncture pairs on line 489 for treatment of osteoarthritis of the knee only

Line 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT

Acupuncture pairs on Line 562 ~~only~~ with the low back diagnoses (M47.816, M47.817, M47.896, M47.897, M48.36, M48.37, M51.26, M51.27, M51.36, M51.37, M51.86, M51.87, M54.5, M62.830, S33.5xxA, S33.9xxA, S39.092A, S39.82xA, S39.93xA), when referred, for up to 12 sessions. Acupuncture pairs with chronic (>90 days) neck pain diagnoses (723.1, 723.8, 723.9, 847.0), when referred, for up to 12 sessions.

Line 563 TENSION HEADACHES

Acupuncture is included on Line 563 for treatment of tension headaches, when referred, for up to 12 sessions.

Lung Volume Reduction Surgery

Question: Should a guideline be added to specify which patients qualify for lung volume reduction surgery for emphysema?

Question source: DMAP

Issue: In December, 2011, the HOSC added a 2012 CPT code (32672) to line 306 CHRONIC OBSTRUCTIVE PULMONARY DISEASE; CHRONIC RESPIRATORY FAILURE and moved an existing lung volume reduction surgery (32491) from the Excluded List to Line 306. DMAP is requesting that the HERC review this procedure and consider a guideline to specify which patients qualify for this surgery.

Lung volume reduction surgery (LVRS) or reduction pneumoplasty, also referred to as lung shaving or lung contouring, is performed on patients with severe emphysema in order to allow the remaining compressed lung to expand, and thus, improve respiratory function. However, it has significant peri-operative morbidity and mortality. LVRS is associated with a 5–8% operative mortality, 30–40% morbidity and a cost of $20–35 000 for each surgical procedure (Berger 2005).

December, 2011 HOSC minutes

> 32672 (Thoracoscopy, surgical; with resection-plication for emphysematous lung (bullous or non-bullous) for lung volume reduction (LVRS), unilateral includes any pleural procedure, when performed): Gubler noted that this procedure is used for recurrent pneumothorax in bullous emphysema. Shaffer noted that DMAP gets requests for authorization for this procedure. As the alternative is lung transplant, DMAP is authorizing this procedure as a less costly option. Olson wondered if a guideline should be created to restrict use of this procedure to recurrent pneumothorax. Gubler felt that this procedure was done very rarely and not abused. Price noted that DMAP as authorized 2 requests for this procedure in the past 5 years, so it is a rare procedure. The decision was to place on the COPD line (306) rather than on the Excluded List. The existing similar code (32491) was moved from the Excluded list to line 206 was well.

From DMAP

> It came to the attention of DMAP via the RN Hotline call from a CCO that the CPT 32491 (Lung Volume Reduction Surgery) was to be removed from the Excluded List and placed on line 306 of the OHP Prioritized List based on the 2/14/2012 "Dear Honorables" letter effective 4/1/2012 by HERC. DMAP did not make changes in the Medical Management Information Systems or Med-Surgical Rules at that time (this code continues in rule as not covered OAR 410-130-0220-1 Table).
>
> This was discussed in Medical Management Committee 1/22/2013. While policy can revise the rules and open the code for payment it was thought that it should require prior

authorization. EncoderPro indicates that the only allowable diagnoses for this procedure are 492.0 (Emphysematous Bleb) and 492.8 (Other Emphysema). These codes are included on line 306 to pair with the 32491 procedure code. Also included on line 306 are less definitive diagnosis codes such as 496 (COPD) which would not be appropriate and support the need for the procedure. Information was provided by the Transplant Coordinator that this procedure is considered in lieu of or bridge to lung transplants. Line 254 for Lung Transplants includes the specific diagnosis of 492.8 (Other Emphysema) to pair with transplants codes but the CPT code 32491 is not included on this line.

DMAP is requesting feedback on whether this procedure might necessitate a guideline note for specific coverage criteria as paired on line 306 or would a "coding specification" be appropriate to define that this procedure code is included on this line and intended to pair only with the specific diagnosis code(s) as noted above? If a coding specification is appropriate then DMAP can limit that procedure code to be reimbursed only if paired with those specific diagnoses. This would eliminate the need or concern to place a prior authorization requirement on it and define coverage criteria.

Evidence

1) **Berger 2005**, meta-analysis of RCTs
    a. N=6 studies (306 patients)
    b. 3-12 month follow up
    c. The LVRS arm of the meta-analysis population showed better results than the medical cohort in terms of pulmonary function (FEV1 $p < 0.0001$, FVC $p < 0.0001$, residual volume $p < 0.0001$, total lung capactiy $p = 0.004$), gas exchange (arterial partial pressure of oxygen $p < 0.0001$) and exercise capacity (6MWD $p = 0.0002$)
    d. Mortality 6–12 months after random assignment to treatment was similar in the two study arms, suggesting that the operative mortality from LVRS was offset, within months, by deaths in the medical arm.
    e. Conclusions: This meta-analysis showed that a selected subset of patients with advanced, heterogeneous emphysema and low exercise tolerance (6MWD) experienced better outcomes from LVRS than from medical therapy.
2) **Miller 2006**, Canadian RCT LVRS vs best medical care (BMC)
    a. RCT, 2 yr follow up
    b. N=62 patients
    c. Overall surgical mortality was 16% at 2 years while the overall medical mortality was 13% ($p = 0.914$). There were no 30-day postoperative deaths but 2 deaths (6%) occurred within 90 days of randomization.
    d. Surgery reduced the residual volume measured at 6 months by 23% (5,385 mL to 4,322 mL, $p = 0.007$). There was an increase in forced expiratory volume in 1 second (FEV1) of 30% (265 mL, $p = 0.013$) from baseline, an improvement in the six minute walk test (6MWT) of 78 meters ($p = 0.045$), and an increase in Health Utility Index 3 (HUI3) which peaked at 6 months with a difference of 0.16 ($p = 0.129$). There was a gain in QALYs of 0.21 ($p = 0.19$) in the LVRS-arm over the

BMC-arm. The LVRS costs an additional $28,119 Canadian dollars (CAD) compared with BMC or $133,900/QALY gained.

3) **Naunheim 2006**, National Emphysema Treatment Trial predictors of morbidity and mortality
    a. N=511 with LVRS
    b. The incidence of operative mortality was 5.5%, major pulmonary morbidity occurred in 29.8% of patients, and cardiovascular morbidity occurred in 20.0% of patients. Predictors for these end points are as follows: Non–upper-lobe predominance predicted operative mortality. Pulmonary morbidity increased in elderly patients with a low DLCO. Cardiovascular morbidity increased in older, steroid dependent patients with non-upper lobe predominance

Other coverage policies

1) CMS 2005
    a. Medicare-covered LVRS approaches are limited to bilateral excision of a damaged lung with stapling performed via median sternotomy or video-assisted thoracoscopic surgery.
    b. Qualifying patients
        i. BMI ≤31.1 kg/m2 (men) or ≤32.3 kg/m 2 (women)
        ii. Stable with ≤20 mg prednisone (or equivalent) qd
        iii. CT evidence of bilateral emphysema
        iv. Forced expiratory volume in one second (FEV_1) ≤ 45% predicted ≥ 15% predicted if age ≥ 70 years)
        v. Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
        vi. Residual volume (RV) ≥ 150% predicted post-bronchodilator
        vii. PCO_2, ≤ 60 mm Hg (PCO_2, ≤ 55 mm Hg if 1-mile above sea level)
        viii. PO_2, ≥ 45 mm Hg on room air (PO_2, ≥ 30 mm Hg if 1-mile above sea level)
        ix. Post-rehabilitation 6-min walk of ≥ 140 m; able to complete 3 min unloaded pedaling in exercise tolerance test (pre- and post-rehabilitation)
        x. Plasma cotinine level ≤13.7 ng/mL (or arterial carboxyhemoglobin ≤ 2.5% if using nicotine products)
        xi. Nonsmoking for 4 months prior to initial interview and throughout evaluation for surgery
        xii. Severe upper lobe predominant emphysema (as defined by radiologist assessment of upper lobe predominance on CT scan) OR severe non-upper lobe emphysema with low exercise capacity
    c. Performed at an approved facility: certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program (program standards and requirements as printed in the Joint Commission's October 25, 2004, Disease Specific Care Certification Program packet); or (2) approved as Medicare lung or heart-lung transplantation hospitals.

2) Cigna 2012
    a. Cigna covers lung volume reduction surgery (LVRS) for individuals with severe emphysema when ALL of the following criteria are met:

i. radiological evidence of bilateral upper-lobe (heterogeneous) emphysema
ii. smoking cessation for at least six months
iii. low functional capacity after pulmonary rehabilitation
iv. pulmonary function test results showing:
    1. forced expiratory volume in one second (FEV1) ≤ 45% of predicted and, if age 70 or older, FEV1 ≥15% of predicted value
    2. post-bronchodilator total lung capacity (TLC) ≥100% of predicted and residual volume (RV) ≥ 150% of predicted value
v. resting partial pressure of oxygen (PaO2) ≥45 mm Hg and resting partial pressure of carbon dioxide (PaCO2) ≤60 mm Hg on room air
vi. six-minute walk test > 140 meters

Summary: LVRS is a high cost, high mortality and morbidity procedure which is effective only in select patients with bilateral upper lobe predominant emphysema who are not current smoking and have a specific set of test parameters.

Recommendation:

1) Consider moving lung volume reduction surgery from line 306 to the Excluded List
    a. High morbidity and mortality
    b. High cost per QALY

   OR

2) Add the following guideline to line 306 CHRONIC OBSTRUCTIVE PULMONARY DISEASE; CHRONIC RESPIRATORY FAILURE

GUIDELINE NOTE XXX LUNG VOLUME REDUCTION SURGERY

Line 306

Lung volume reduction surgery (LVRS, CPT 32491, 32672) is included on line 306 only for treatment of patients with radiological evidence of severe bilateral upper lobe predominant emphysema (ICD-9 492.0, 492.8) and all of the following:

1) BMI ≤31.1 kg/m2 (men) or ≤32.3 kg/m 2 (women)
2) Stable with ≤20 mg prednisone (or equivalent) dose a day
3) Pulmonary function testing showing
    a. Forced expiratory volume in one second (FEV_1) ≤ 45% predicted and, if age 70 or older, FEV_1 ≥ 15% predicted value
    b. Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
    c. Residual volume (RV) ≥ 150% predicted post-bronchodilator
4) PCO_2, ≤ 60 mm Hg (PCO_2, ≤ 55 mm Hg if 1-mile above sea level)
5) PO_2, ≥ 45 mm Hg on room air (PO_2, ≥ 30 mm Hg if 1-mile above sea level)
6) Post-rehabilitation 6-min walk of ≥ 140 m
7) Non-smoking for 6 months prior to surgery, as shown by cotinine level

The procedure must be performed at an approved facility (1) certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program or (2) approved as Medicare lung or heart-lung transplantation hospitals. The patient must have approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist post-rehabilitation. The patient must have approval for surgery by cardiologist if any of the following are present: unstable angina; left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram; LVEF <45%; dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (>5 premature ventricular contractions per minute; cardiac rhythm other than sinus; premature ventricular contractions on EKG at rest).

ORIGINAL RESEARCH ARTICLE

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Lung Volume Reduction Surgery

A Meta-Analysis of Randomized Clinical Trials

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Abstract

Background: Observational studies have suggested that lung volume reduction surgery (LVRS) is superior to optimal medical therapy for selected subsets of patients with advanced emphysema. Randomized clinical trials (RCTs) with the exception of the National Emphysema Treatment Trial (NETT), failed to enroll a sufficient number of patients to provide clinicians and patients with convincing outcome data on the usefulness of LVRS. It was postulated that a meta-analysis of these RCTs (3–12 months' follow up) may provide more compelling information on the value of LVRS in patients with emphysema.

Methods: A comprehensive search of the MEDLINE database between January 1994 and January 2004 for RCTs on LVRS was performed.

Results: From a total of eight RCTs on record, six studies (306 patients) with 3- to 12-month follow up were deemed suitable for meta-analysis. Key baseline features of these RCT populations included heterogeneous emphysema, comparable inclusion/exclusion criteria and, in retrospect, low walking capacity as measured by the 6-minute walk distance (6MWD). This profile closely resembles NETT's 'predominantly upper lobe – low exercise tolerance emphysema' cohort.

The LVRS arm of the meta-analysis population showed better results than the medical cohort in terms of pulmonary function (FEV_1 $p < 0.0001$, FVC $p < 0.0001$, residual volume $p < 0.0001$, total lung capactiy $p = 0.004$), gas exchange (arterial partial pressure of oxygen $p < 0.0001$) and exercise capacity (6MWD $p = 0.0002$). Although information on quality-of-life measures was not sufficiently uniform to qualify for meta-analysis, a survey of available data revealed better results in the surgical than in the medical arms of each RCT. Mortality 6–12 months after random assignment to treatment was similar in the two study arms, suggesting that the operative mortality from LVRS was offset, within months, by deaths in the medical arm.

Conclusions: This meta-analysis showed that a selected subset of patients with advanced, heterogeneous emphysema and low exercise tolerance (6MWD) experienced better outcomes from LVRS than from medical therapy.

Pulmonary emphysema is a chronic disease that is crippling, and frequently fatal. The disease is caused, almost exclusively, by tobacco use and manifested by progressive shortness of breath with poor exercise tolerance. It is estimated that the condition afflicts 3.1 million Americans.[1] The pathologic process destroys the lung tissue and results in hyperinflation of the parenchyma with loss of elastic recoil. Medical therapy, including pulmonary rehabilitation, often fails to provide sufficient relief to permit the

A Randomized Clinical Trial of Lung Volume Reduction Surgery Versus Best Medical Care for Patients With Advanced Emphysema: A Two-Year Study From Canada

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Background. **We present a summary report evaluating the efficacy of lung volume reduction surgery (LVRS) in patients with advanced emphysema in the Canadian setting.**

Methods. **Quality of Life measures assessed the efficacy of adding LVRS to best medical care including rehabilitation in this blinded randomized multicentered controlled trial with 2 years of follow-up. Health utility and quality-adjusted life years (QALY) were outcomes central to our economic assessment.**

Results. **None of the 32 patients randomized to the LVRS arm or 30 patients in the best medical care (BMC) arm crossed-over and no patients were lost to follow-up. Overall surgical mortality was 16% at 2 years while the overall medical mortality was 13% ($p = 0.914$). There were no 30-day postoperative deaths but 2 deaths (6%) occurred within 90 days of randomization. Surgery reduced the residual volume measured at 6 months by 23% (5,385 mL to 4,322 mL, $p = 0.007$). There was an increase in forced expiratory volume in 1 second (FEV_1) of 30% (265 mL, $p = 0.013$) from baseline, an improvement in the six minute walk test (6MWT) of 78 meters ($p = 0.045$), and an increase in Health Utility Index 3 (HUI3) which peaked at 6 months with a difference of 0.16 ($p = 0.129$). There was a gain in QALYs of 0.21 ($p = 0.19$) in the LVRS-arm over the BMC-arm. The LVRS costs an additional $28,119 Canadian dollars (CAD) compared with BMC or $133,900/QALY gained.**

Conclusions. **The addition of LVRS to best medical care including pulmonary rehabilitation improves pulmonary function, exercise activity, and quality of life in selected patients with advanced emphysema. Cost is high but in keeping with other treatment modalities currently available.**

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Chronic obstructive pulmonary disease is the fifth most common cause of death and is the only leading cause of death that is rising in prevalence. Despite the results of seven randomized trials and several case series demonstrating a benefit to patients, physicians remain routinely reluctant to recommend surgery to their patients with emphysema as a palliative measure [1–10]. Information about the risks, benefits, and costs of lung volume reduction in a Canadian setting has been lacking. We report the final clinical and economic results of a multicenter Canadian trial with 2-year follow-up.

Patients and Methods

Patient Selection

Five Canadian centers enrolled patients into the CLVR study conditional on specific inclusion and exclusion criteria (Table 1). Patients were not excluded for homogeneous disease. After screening, patients who qualified for the trial were referred for a standardized pulmonary rehabilitation program. Medical therapy was optimized [11], baseline testing (prerandomization) was performed (Table 2), and patients who qualified were randomized in a 1:1 allocation ratio between lung volume reduction surgery (LVRS) and optimal medical therapy. Patients assigned to LVRS proceeded to surgery within 2 weeks. All outcome events were attributed on an intent-to-treat basis. Crossover between study arms was not permitted. Recruitment started July 1997 and finished January 2001. Institutional ethics approval of this study was obtained on June 1996 and each patient within the study gave informed consent for serving as a subject.

Surgical Technique and Best Medical Care

Surgical technique was standardized. Preoperative high resolution computed tomographic scan and ventilation-perfusion scan were used to determine target areas that were resected through a median sternotomy. Approximately 20% to 30% of the total lung volume was removed and the staple line was buttressed with either bovine

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Predictors of operative mortality and cardiopulmonary morbidity in the National Emphysema Treatment Trial

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Objective: We sought to identify predictors of operative mortality, pulmonary morbidity, and cardiovascular morbidity after lung volume reduction surgery.

Methods: Univariate and multivariate logistic regression analyses were performed. Candidate predictors included demographic characteristics, physical condition characteristics, pulmonary function measures, measures of the distribution of emphysema as determined by radiologists and by means of computerized analysis of chest computed tomographic scans, and measures of exercise capacity, dyspnea, and quality of life. End points analyzed were operative mortality (death within 90 days of the operation), major pulmonary morbidities (tracheostomy, failure to wean, reintubation, pneumonia, and ventilator for ≥3 days), and cardiovascular morbidities (infarction, pulmonary embolus, or arrhythmia requiring treatment).

Results: Five hundred eleven patients in the non–high-risk group of the National Emphysema Treatment Trial underwent lung volume reduction. The incidence of operative mortality was 5.5%, major pulmonary morbidity occurred in 29.8% of patients, and cardiovascular morbidity occurred in 20.0% of patients. Predictors for these end points are as follows:

		Relative odds	*P* value
Operative mortality	Non–upper-lobe predominance (radiologist)	2.99	.009
Pulmonary morbidity	Age in years	1.05	.02
	FEV_1 % predicted	0.97	.05
	D_{LCO} % predicted	0.97	.01
Cardiovascular morbidity	Age in years	1.07	.004
	Oral steroid use	1.72	.04
	Non–upper-lobe predominance (QIA α measure)	2.67	<.001

FEV_1, Forced expiratory volume in 1 second; *D_{LCO}*, diffusion capacity; *QIA*, quantitative image analysis.

Conclusions: Although lung volume reduction can be performed in selected patients with acceptable mortality, the incidence of major cardiopulmonary morbidity remains high. The lone predictor for operative mortality of lung volume reduction was the presence of non–upper-lobe-predominant emphysema, as assessed by the radiologist. Pulmonary morbidity can be expected in elderly patients who have a low diffusing capacity for carbon monoxide and forced expiratory volume in 1 second. When assessing morbidity, the computer-assisted chest computed tomographic analysis proved useful only in predicting cardiovascular complications.

National Coverage Determination (NCD) for Lung Volume Reduction Surgery (Reduction Pneumoplasty) (240.1)

- Expand All
- Collapse All

Tracking Information

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240.1

Manual Section Title

Lung Volume Reduction Surgery (Reduction Pneumoplasty)

Version Number

3

Effective Date of this Version

11/17/2005

Implementation Date

3/2/2006

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Description Information

Benefit Category
Inpatient Hospital Services
Outpatient Hospital Services Incident to a Physician's Service
Physicians' Services
Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description

A. General

Lung volume reduction surgery (LVRS) or reduction pneumoplasty, also referred to as lung shaving or lung contouring, is performed on patients with severe emphysema in order to allow the remaining compressed lung to expand, and thus, improve respiratory function. Medicare-covered LVRS approaches are limited to bilateral excision of a damaged lung with stapling performed via median sternotomy or video-assisted thoracoscopic surgery.

Indications and Limitations of Coverage

B. Nationally Covered Indications

Effective for services performed on or after January 1, 2004 Medicare will only consider LVRS reasonable and necessary when all of the following requirements are met (note varying dates for facility criteria in section 3. below):

1. The patient satisfies all the criteria outlined below:

Assessment	Criteria
History and physical examination	Consistent with emphysema
	BMI, ≤31.1 kg/m ^{2} (men) or ≤ 32.3 kg/m ^{2} (women)
	Stable with ≤ 20 mg prednisone (or equivalent) qd
Radiographic	High Resolution Computer Tomography (HRCT) scan evidence of bilateral emphysema
Pulmonary function (pre-rehabilitation)	Forced expiratory volume in one second (FEV $_1$) ≤ 45% predicted ≥ 15% predicted if age ≥ 70 years)
	Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
	Residual volume (RV) ≥ 150% predicted post-bronchodilator
Arterial blood gas level (pre-rehabilitation)	PCO $_2$, ≤ 60 mm Hg (PCO $_2$, ≤ 55 mm Hg if 1-mile above sea level)
	PO $_2$, ≥ 45 mm Hg on room air (PO $_2$, ≥ 30 mm Hg if 1-mile above sea level)
Cardiac assessment	Approval for surgery by cardiologist if any of the following are present: Unstable angina; left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram; LVEF <45%; dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (>5 premature ventricular contractions per minute; cardiac rhythm other than sinus; premature ventricular contractions on EKG at rest)
Surgical assessment	Approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist post-rehabilitation
Exercise	Post-rehabilitation 6-min walk of ≥ 140 m; able to complete 3 min unloaded pedaling in exercise tolerance test (pre- and post-rehabilitation)
Consent	Signed consents for screening and rehabilitation
Smoking	Plasma cotinine level ≤13.7 ng/mL (or arterial carboxyhemoglobin ≤ 2.5% if using nicotine products)
	Nonsmoking for 4 months prior to initial interview and throughout evaluation for surgery
Preoperative diagnostic and therapeutic program adherence	Must complete assessment for and program of preoperative services in preparation for surgery

2. In addition, the patient must have:

- Severe upper lobe predominant emphysema (as defined by radiologist assessment of upper lobe predominance on CT scan), or
- Severe non-upper lobe emphysema with low exercise capacity.

Patients with low exercise capacity are those whose maximal exercise capacity is at or below 25 watts for women and 40 watts (w) for men after completion of the preoperative therapeutic program in preparation for LVRS. Exercise capacity is measured by incremental, maximal, symptom-limited exercise with a cycle ergometer utilizing 5 or 10 watt/minute ramp on 30% oxygen after 3 minutes of unloaded pedaling.

3. Effective for services performed on or after November 17, 2005, CMS determines that LVRS is reasonable and necessary when performed at facilities that are:

(1) certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program (program standards and requirements as printed in the Joint Commission's October 25, 2004, Disease Specific Care Certification Program packet); or (2) approved as Medicare lung or heart-lung transplantation hospitals.

In addition, LVRS performed between January 1, 2004, and May 17, 2007, is reasonable and necessary when performed at facilities that: (1) were approved by the National Heart Lung and Blood Institute to participate in the National Emphysema Treatment Trial (NETT); or (2) are approved as Medicare lung or heart-lung transplantation hospitals.

A list of approved facilities and their approval dates will be listed and maintained on the CMS Web site at http://www.cms.gov/MedicareApprovedFacilitie/04_lvrs.asp#TopOfPage.

The surgery must be preceded and followed by a program of diagnostic and therapeutic services consistent with those provided in the NETT and designed to maximize the patient's potential to successfully undergo and recover from surgery. The program must include a 6- to 10-week series of at least 16, and no more than 20, preoperative sessions, each lasting a minimum of 2 hours. It must also include at least 6, and no more than 10, postoperative sessions, each lasting a minimum of 2 hours, within 8 to 9 weeks of the LVRS. This program must be consistent with the care plan developed by the treating physician following performance of a comprehensive evaluation of the patient's medical, psychosocial and nutritional needs, be consistent with the preoperative and postoperative services provided in the NETT, and arranged, monitored, and performed under the coordination of the facility where the surgery takes place.

C. Nationally Non-covered Indications

1. LVRS is not covered in any of the following clinical circumstances:

a. Patient characteristics carry a high risk for perioperative morbidity and/or mortality;
b. The disease is unsuitable for LVRS;
c. Medical conditions or other circumstances make it likely that the patient will be unable to complete the preoperative and postoperative pulmonary diagnostic and therapeutic program required for surgery;
d. The patient presents with FEV1 ≤ 20% of predicted value, and either homogeneous distribution of emphysema on CT scan, or carbon monoxide diffusing capacity of ≤ 20% of predicted value (high-risk group identified October 2001 by the NETT); or
e. The patient satisfies the criteria outlined above in section B(1), and has severe, non-upper lobe emphysema with high exercise capacity. High exercise capacity is defined as a maximal workload at the completion of the preoperative diagnostic and therapeutic program that is above 25 w for women and 40 w for men (under the measurement conditions for cycle ergometry specified above).

2. All other indications for LVRS not otherwise specified remain noncovered.

(This NCD last reviewed November 2005.)

Claims Processing Instructions

- Claims Processing Manual TN 768

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Transmittal Information

Transmittal Number

44

Coverage Transmittal Link

http://www.cms.gov/transmittals/downloads/R44NCD.pdf

Revision History

12/1995 - Provided noncoverage policy. Effective date NA. (TN 83)

07/1997 - Provided coverage policy. Effective date 08/11/1997. (TN 102)

11/2003 - Expanded coverage to include patients who are: (1) Non high-risk and present with severe, upper-lobe emphysema; or, (2) Non high-risk and present with severe, non upper-lobe emphysema with low exercise capacity. Effective date 1/01/2004. Implementation date 1/5/2004. M+C Implementation date 4/5/2004. (TN 3) (CR 2688)

12/2005 - Modified requirements for facilities eligible to perform lung volume reduction surgery. Effective Date: 11/17/2005. Implementation Date: 03/02/2006. (TN 44) CR4149

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National Coverage Analyses (NCAs)

National Coverage Analyses (NCAs)

This NCD has been or is currently being reviewed under the National Coverage Determination process. The following are existing associations with NCAs, from the National Coverage Analyses database.

- First reconsideration for Lung Volume Reduction Surgery (CAG-00115R) opens in new window
- Second reconsideration for Lung Volume Reduction Surgery (CAG-00115R2) opens in new window

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Additional Information

Other Versions

- Lung Volume Reduction Surgery (Reduction Pneumoplasty)- Version 2, Effective between 1/1/2004 - 11/17/2005
- Lung Volume Reduction Surgery (Reduction Pneumoplasty)- Version 1, Effective between 8/11/1997 - 1/1/2004

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Cigna Medical Coverage Policy

Subject **Lung Volume Reduction Surgery (LVRS)**

Effective Date **11/15/2012**
Next Review Date **11/15/2013**
Coverage Policy Number **0218**

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Lung and Heart-Lung Transplantation
Oxygen for Home Use
Pulmonary Rehabilitation

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Coverage Policy

Cigna covers lung volume reduction surgery (LVRS) for individuals with severe emphysema when ALL of the following criteria are met:

- radiological evidence of bilateral upper-lobe (heterogeneous) emphysema
- smoking cessation for at least six months
- low functional capacity after pulmonary rehabilitation
- pulmonary function test results showing:
  - forced expiratory volume in one second (FEV_1) ≤ 45% of predicted and, if age 70 or older, FEV_1 ≥15% of predicted value
  - post-bronchodilator total lung capacity (TLC) ≥100% of predicted and residual volume (RV) ≥ 150% of predicted value
- resting partial pressure of oxygen (P_aO_2) ≥45 mm Hg and resting partial pressure of carbon dioxide (P_aCO_2) ≤60 mm Hg on room air
- six-minute walk test > 140 meters
- cardiology clearance for the presence of ANY of the following:
  - unstable angina
  - left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram
  - LVEF < 45 %
  - nuclear cardiac scan indicates coronary artery disease (CAD) or ventricular dysfunction
  - arrhythmia with greater than five premature ventricular contractions (PVCs) per minute
  - cardiac rhythm other than normal sinus rhythm (NSR)
  - PVCs on electrocardiogram (EKG) at rest

Cigna does not cover LVRS for any other indication because it is considered experimental, investigational or unproven.

Cigna does not cover bronchoscopic lung volume reduction procedures (e.g., bronchial valve placement, biologic lung volume reduction, bronchopulmonary fenestration) because they are considered experimental, investigational or unproven.

General Background

Pulmonary emphysema is an irreversible condition characterized by progressively increasing dyspnea on exertion and eventually at lower levels of activity. The fine architecture and elasticity of the lungs are destroyed, resulting in obstruction of the airways, trapping of air, and difficulty exchanging oxygen. While there are many known causes of emphysema, including alpha-1-antitrypsin deficiency, cystic fibrosis, air pollution, occupational exposure, and bronchiectasis, the disease process generally results directly from tobacco abuse. The importance of smoking cessation is stressed as the single most effective way to reduce the risk of developing emphysema and stop its progression.

Medical therapy for chronic pulmonary obstructive disease (COPD) due to emphysema typically includes smoking cessation intervention, bronchodilators, anti-inflammatory agents, oxygen, mucolytic drugs, influenza and pneumococcal vaccinations, antibiotics, pulmonary rehabilitation, and alpha-1-antitrypsin replacement therapy in patients who are deficient. Malnutrition is associated with a poor prognosis for patients with COPD, since it predisposes such patients to infections, as well as reducing respiratory muscle force, exercise tolerance and quality of life. Poor nutritional status can be modified through appropriate and efficacious diet therapy and monitoring (Fernandes and Bezerra, 2006). Long-term home oxygen use in hypoxemic patients has been proven to decrease mortality rates, and smoking cessation has been shown to slow the rate of progression of COPD. Surgical treatments available for severe emphysema that is unresponsive to medical therapy include bullectomy for patients with bullous lung disease, lung transplantation, and lung volume reduction surgery.

Lung Volume Reduction Surgery (LVRS)
LVRS involves resecting emphysematous lung tissue, usually from both upper lobes. The procedure may be performed by video-assisted thoracic surgery (VATS) or by median sternotomy. The affected lung tissue is stapled, resected and removed from the chest cavity. Laser excision has been utilized in an attempt to decrease the rate of complication due to air leaks. The goal of the surgery is to reduce the overall volume of the lung by 20–30%, while preserving non-diseased tissue and the normal anatomical shape of the lung. The remaining lung tissue has enhanced recoil and improved gas-exchange properties, which are presumed mechanisms leading to improved survival, functional gains and symptomatic relief. Lung function is improved by reversing the adverse effects of hyperinflation and uneven ventilation, in turn, decreasing the work of breathing and improving alveolar gas exchange. LVRS is palliative, however, not curative; its objective is to improve functional status and quality of life.

Literature Review
The evidence in the published peer-reviewed literature examining the safety and effectiveness of LVRS includes meta-analyses, technology assessments, randomized controlled trials (RCTs), and observational studies (Huang, et al., 2011; Tiong, et al., 2006; Berger, et al., 2005; National Institute for Clinical Excellence [NICE], 2005; Miller, et al., 2005; Goldstein, et al., 2003; Geddes, et al., 2000) with patient populations ranging from 93–1663. In general study results have demonstrated significant improvements in functional capacity with LVRS compared to medical therapy for advanced emphysema. Mortality rates have been reported to be higher after LVRS, ranging from 4%–10%. **Level of Evidence: 1**

The National Emphysema Treatment Trial (NETT) helped to define the subset of patients who might benefit the most from LVRS, as well as those patients who would be at the highest risk for the procedure. The NETT was a multicenter, randomized, controlled clinical trial (n=1218) that compared LVRS (n=608) to medical therapy (n=610) for severe emphysema. Selection criteria for the study included: forced expiratory volume in one second (FEV_1) ≤45%, but ≥15% for patients ≥70 yrs; total lung capacity (TLC) ≥100% predicted; residual volume (RV) ≥150%; resting partial pressure of carbon dioxide (P_aCO_2) ≤60 mm Hg; resting partial pressure of oxygen (P_aO_2)

≥45 mm Hg; six-minute walk test > 140 meters; body mass index (BMI) ≤ 31.1 for males and ≤ 32.3 for females; abstinence from smoking for at least six months and completion of the NETT pulmonary rehabilitation program. Exclusion criteria included the following (Fishman, et al., 2003):

- diffuse emphysema deemed unsuitable for LVRS
- pleural or interstitial disease precluding surgery
- pulmonary nodule requiring surgery
- previous sternotomy or lobectomy
- uncontrolled hypertension
- pulmonary hypertension
- LVEF < 45% AND myocardial infarction or congestive heart failure within the previous six months
- cardiac dysrythmias which might pose a risk during exercise testing
- oxygen requirement that exceeds six liters at rest to maintain saturation level at a minimum of 90%

Maximal functional capacity, pulmonary function as measured by FEV_1, and quality of well-being were found to be higher in the surgical group. The results revealed no difference in overall mortality between the two groups after a mean follow-up observation period of 29 months. The risk of death during the first three months after randomization was higher in the surgical group than in the medical treatment group,

Researchers found that two characteristics helped predict if an individual participant would benefit from LVRS: whether the emphysema was concentrated in the upper lobes of the lungs and whether functional capacity was low or high. For those in the LVRS group, functional capacity was measured after medical therapy but before surgery. A functional capacity score ≤ 25 W for females or ≤ 40 W for males was considered low; a score > 25 W for females or > 40 W for males was considered high. The NETT suggested that the best predictors of postsurgical improvement are upper-lobe predominance emphysema and low postrehabilitation functional capacity, measured while breathing 30% inspiratory oxygen fraction on cycle ergometry.

Naunheim et al. (2006) presented an updated analysis of NETT data at a median follow-up of 4.3 years. The evidence for differential risk and benefit after LVRS in the four subgroups defined by baseline exercise capacity (i.e., low versus high) and distribution of emphysema (i.e., upper-lobe versus non-upper-lobe) persisted in this analysis. The following observations were reported:

1. For patients with predominantly upper-lobe emphysema and low postrehabilitation exercise capacity, the additional data confirmed the beneficial effects of LVRS. The survival advantage of the LVRS group over the medical treatment group that was previously demonstrated after a median of 2.4 years of follow-up (p=0.005) was sustained in the longer follow-up period (p=0.01). Long-term follow-up strongly supports the performance of LVRS in this subgroup that comprised 24% of the NETT population.

2. For patients with upper-lobe disease and high postrehabilitation exercise capacity, LVRS had no survival advantage or disadvantage. Patients in this subgroup (34% of all enrolled patients) who are looking primarily for symptomatic improvement may benefit from LVRS.

3. Patients with non-upper-lobe-predominant emphysema and low postrehabilitation exercise capacity had limited improvement in exercise capacity regardless of treatment. Survival was not found to be different between the LVRS and medical groups. Recommendations regarding LVRS in this subgroup are guarded because the primary benefit is improvement in HRQL, which appears to dissipate within three years after surgery.

4. For patients in the subgroup characterized by non-upper-lobe-predominant emphysema and high postrehabilitation maximum work, LVRS initially led to a higher mortality. Extended follow-up confirmed that these patients have little chance of functional or symptomatic improvement and, therefore, are poor candidates for LVRS.

The authors also noted that extended follow-up revealed a survival advantage with LVRS for the entire NETT population. It was concluded that the “effects of LVRS are durable, and it can be recommended for upper-lobe-predominant emphysema patients with low exercise capacity. LVRS should be considered for palliation in patients with upper-lobe emphysema and high exercise capacity” (Naunheim, et al., 2006).

Bronchoscopic Lung Volume Reduction Procedures
Minimally invasive techniques to attain lung volume reduction without open thoracotomy are under investigation. Inclusion and exclusion criteria for bronchoscopic emphysema treatment strategies are similar to those used for LVRS. Bronchoscopic devices and techniques being evaluated include (Berger, et al., 2010):

- one-way bronchial valves inserted by fiberoptic bronchoscopy to promote atelectasis in the emphysematous lung (e.g., Endobronchial Valve [EBV], Emphasys Medical Inc., Redwood City, CA)
- deployment of a biodegradable gel into bronchi to collapse targeted hyperinflated pulmonary parenchyma and initiate an inflammatory response to selectively reduce the volume of treated lung (Biologic Lung Volume Reduction [BioLVR], Aeris Therapeutics, Inc. Woburn, MA)
- bronchopulmonary fenestrations to enhance expiratory flow (e.g., Airway Bypass Tracts [ABT], Broncus Inc. Mountain View, CA)

None of these devices have been approved by the U.S. Food and Drug Administration (FDA) for use in the U.S. for any indication

Literature Review: The evidence in the published peer-reviewed medical literature evaluating the safety and effectiveness of bronchoscopic lung volume reduction procedures for severe emphysema consists of few observational studies with small patient populations (range 13–50) and primarily short-term follow-up (Venuta, et al., 2012; Kotecha, et al., 2011; Refaely , et al., 2010; Criner, et al., 2009; Wood, et al., 2007; Venuta, et al., 2005). Preliminary results suggest that bronchoscopic approaches may be associated with lower mortality and morbidity than LVRS, but with decreased effectiveness.

Shah et al. (2011) conducted a multicenter randomized, double-blind, sham-controlled study (n=315) in which patients with severe homogeneous emphysema were assigned to either airway bypass (n=208) or sham control (n=107). At six-month follow-up, no difference was found between treatment and control groups in terms of the co-primary efficacy endpoint (improvement in forced vital capacity [FVC] of ≥12% and decrease of ≥ one point in dyspnea score from baseline).

A 2009 guidance from NICE states that “the current evidence on the efficacy of bronchoscopic lung volume reduction with airway valves for advanced emphysema shows some improvement in patient-reported quality of life outcomes but there is inadequate evidence of improvement based on objective outcomes of efficacy. There are no major safety concerns in the short term, but there is inadequate evidence on safety in the long term.”

Larger, well designed studies are needed to demonstrate the efficacy of these procedures for the treatment of advanced emphysema. There is insufficient evidence in the published peer-reviewed literature to support any of the bronchoscopic lung volume reduction procedures for this condition.

Professional Societies/Organizations
The 2004 ATS and European Respiratory Society (ERS) guidelines for the diagnosis and management of COPD state that “LVRS may result in improved spirometry, lung volumes, exercise capacity, dyspnea, HRQL, and possibly survival in highly selected patients” (Celli and McNee, 2004).

The Centers for Medicare & Medicaid Services (CMS) revised its policy on LVRS in 2003. This policy states that patients who are suitable for LVRS must be non-high-risk as defined by NETT and present with severe upper-lobe predominant emphysema, or severe non-upper-lobe emphysema with low exercise capacity. In addition, patients must satisfy all of the following criteria (CMS, 2003):

Assessment	Criteria
History and physical examination	Consistent with emphysema
	Body mass index (BMI), ≤ 31.1 kg/m (men) or ≤ 32.3 kg/m (women)
	Stable with ≤ 20 mg prednisone (or equivalent) once per day

Radiographic	High Resolution Computer Tomography (HRCT) scan evidence of bilateral emphysema
Pulmonary function (pre-rehabilitation)	Forced expiratory volume in one second (FEV) ≤ 45% predicted (≥ 15% predicted if age ≥ 70 years)
	Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
	Residual volume (RV) ≥ 150% predicted post-bronchodilator
Arterial blood gas level (pre-rehabilitation)	PCO_2, ≤ 60 mm Hg (PCO_2, ≤ 55 mm Hg if one mile above sea level)
	PO_2, ≥ 45 mm Hg on room air (PO_2, ≥ 30 mm Hg if one mile above sea level)
Cardiac assessment	Approval for surgery by cardiologist if any of the following are present: Unstable angina; left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram; LVEF < 45%; dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (> five premature ventricular contractions per minute; cardiac rhythm other than sinus; premature ventricular contractions on EKG at rest)
Surgical assessment	Approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist post-rehabilitation
Exercise	Post-rehabilitation six-minute walk of ≥ 140 meters (m); able to complete three-minute unloaded pedaling in exercise tolerance test (pre- and post-rehabilitation)
Consent	Signed consents for screening and rehabilitation
Smoking	Plasma cotinine level ≤ 13.7 ng/mL (or arterial carboxyhemoglobin ≤ 2.5% if using nicotine products) Nonsmoking for four months prior to initial interview and throughout evaluation for surgery
Preoperative diagnostic and therapeutic program adherence	Must complete assessment for and program of preoperative services in preparation for surgery

The CMS states that patients with the following clinical circumstances are not candidates for LVRS:

- high risk for perioperative morbidity and/or mortality
- disease that is unsuitable for LVRS
- medical conditions or other circumstances that render the patient unable to complete the preoperative and postoperative pulmonary diagnostic and therapeutic program required for surgery
- FEV_1 ≤ 20% of predicted value, and either homogeneous distribution of emphysema on CT scan, or DLCO ≤ 20% of predicted value (i.e., high-risk group identified by the NETT)
- severe, non-upper lobe emphysema with high exercise capacity (i.e., maximum workload > 25 W (Watts) for women and > 40 W for men, cycling for three minutes while breathing 30% oxygen)

The American Thoracic Society's (ATS) position statement of May 1996 recommends that LVRS be performed in institutions where a multidisciplinary team, including pulmonologists and thoracic surgeons and a high level of diagnostic and surgical expertise, are available. Patients undergoing LVRS should have advanced emphysema with disabling dyspnea and evidence of severe air trapping. Advanced age (i.e., > age 75) and significant comorbid illness have been considered contraindications to LVRS (ATS, 1996).

Summary

The peer-reviewed literature contains sufficient evidence to conclude that LVRS is indicated for the treatment of patients with end-stage, severe bilateral, upper-lobe emphysema and disabling dyspnea with low functional capacity after a course of pulmonary rehabilitation. LVRS has been shown to produce significant improvement in pulmonary function, dyspnea, functional capacity, and general health-related quality of life (HRQL) for this subset of individuals. LVRS is associated with increased survival and decreased mortality rates for those with predominantly upper-lobe disease and low functional capacity in comparison to those with non-upper-lobe disease.

The evidence in the peer-reviewed scientific literature does not support the safety and effectiveness of bronchoscopic lung volume reduction procedures for any indication, including the treatment of emphysema.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	**Description**
32491	Removal of lung, other than total pneumonectomy; excision-plication of emphysematous lung(s) (bullous or non-bullous) for lung volume reduction, sternal split or transthoracic approach, includes any pleural procedure, when performed

HCPCS Codes	**Description**
G0302	Preoperative pulmonary surgery services for preparation for LVRS, complete course of services, to include a minimum of 16 days of services
G0303	Preoperative pulmonary surgery services for preparation for LVRS, 10 to 15 days of services
G0304	Preoperative pulmonary surgery services for preparation for LVRS, 1 to 9 days of services
G0305	Postdischarge pulmonary surgery services after LVRS, minimum of 6 days of services

ICD-9-CM Diagnosis Codes	**Description**
492.0	Emphysematous bleb
492.8	Other emphysema

Experimental/Investigational/Unproven/Not Covered when used to report bronchoscopic lung volume reduction procedures:

CPT®* Codes	**Description**
31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe **(New code effective 1/1/2013)**
31648	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe **(New code effective 1/1/2013)**
31649	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure) **(New code effective**

	1/1/2013)
31651	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure(s)) **(New code effective 1/1/2013)**
31899	Unlisted procedure, trachea, bronchi
0250T	Airway sizing and insertion of bronchial valve(s), each lobe (List separately in addition to code for primary procedure) **Code deleted 12/31/2012**
0251T	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe **Code deleted 12/31/2012**
0252T	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure) **Code deleted 12/31/2012**

ICD-9-CM Diagnosis Codes	**Description**
492.0	Emphysematous bleb
492.8	Other emphysema

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
Cigna HealthCare	11/15/2007	0218	Lung Volume Reduction Surgery (LVRS)
Great-West Healthcare	10/26/2006	96.243.04	Lung Volume Reduction Surgery

Bilateral cochlear implants for sensorineural hearing loss

Question: How should the guidelines on cochlear implantation be clarified with regard to bilateral cochlear implants for sensorineural hearing loss?

Question source: OHP Managed Care Medical Director, Doug Luther

Issue: The guideline is not specific about whether bilateral cochlear implants for sensorineural hearing loss are intended to be covered. Because the person with a single cochlear implant may have corrected hearing, it is not clear if they are eligible to have the guideline applied for the second ear. DMAP has currently been allowing coverage of bilateral cochlear implants. Also, there are no definitions as to "severe" and "profound" hearing loss in the current guideline language.

Prioritized List Status

GUIDELINE NOTE 31, COCHLEAR IMPLANTATION, AGE 5 AND UNDER

Line 298

Children will be considered candidates for cochlear implants if the following criteria are met:

A) Profound sensorineural hearing loss in both ears
B) Child has reached the age of 1
C) Receive little or no useful benefit from hearing aids
D) No medical contraindications
E) High motivation and appropriate expectations (both child, when appropriate, and family)

GUIDELINE NOTE 49, COCHLEAR IMPLANTS, OVER AGE 5

Line 491

Children will be considered candidates for cochlear implants if the following criteria are met:

1) Profound sensorineural hearing loss in both ears
2) Receive little or no useful benefit from hearing aids
3) No medical contraindications
4) High motivation and appropriate expectations (both child, when appropriate, and family)

Postlinguistic adults will be considered candidates for cochlear implants if the following criteria are met:

1) Severe to profound sensorineural hearing loss in both ears
2) Hearing loss acquired after learning oral speech and language development (postlinguistic hearing loss)

3) Receive limited benefit from appropriately fit hearing aids; i.e., scores of 40% or less on sentence recognition test in the best-aided listening condition
4) No medical contraindications

Prelinguistic adults will be considered candidates for cochlear implants if the following criteria are met:

1) Profound sensorineural hearing loss in both ears
2) Hearing loss acquired before learning oral speech and language development (prelinguistic hearing loss)
3) Receive no benefit from hearing aids
4) No medical contraindications
5) A desire to be a part of the hearing world

Evidence review

MED Report, 2011 reviewing bilateral cochlear implants in children

1) Based on 1 systematic review (Sparreboom 2010) and two Technology Assessments (Bond 2009; Hayes 2009) and a single clinical practice guideline (NICE 2009)
2) The normal hearing range is considered to be from 0 to 140 decibels (dB). Severe hearing loss is defined as the ability to hear loud sounds of 71 to 90 dB, whereas profound loss is regarded as the inability to hear any speech and only loud sounds above 90 dB.
3) Efficacy – bilateral cochlear implants result in improvement in sensitivity to sound (13% improvement ($p<0.0001$) and speech perception (20% improvement, no p value) compared to unilateral implants. Main benefits are in noisy situations. None of the studies included in this report addressed the effects these interventions have on the key patient-oriented outcomes of speech production, educational success, or the quality of life of either deaf children or their parents.
4) Studies funded by device manufacturers and moderate to poor quality.
5) Risks – major complications occur in 7% of cases, including fatal pneumococcal meningitis. 20% have minor complications.
6) Limitations – major limitations about the quality of the evidence including:

   • Small sample size
   • Weak study design
   • Non-randomized study populations
   • No separate control groups (subjects acted as their own controls)
   • Multiple devices used, even in the same patient
   • Funding sources not identified or funded by device manufacturers
   • Variety of follow-up periods presented
   • Diverse outcome measures and testing conditions employed
7) Simultaneous rather than sequential is more cost-effective

Recent study (identified by MED)

Boons, 2012

1) Case-control retrospective study
2) Centers in Belgium and Holland
3) 25 children with 1 cochlear implant matched with 25 children with 2 cochlear implants out of 288 children receiving implants
4) Results: On the receptive language tests (mean difference [95% CI], 9.4 [0.3-18.6]) and expressive language tests (15.7 [5.9-25.4] and 9.7 [1.5-17.9]), children undergoing bilateral implantation performed significantly better than those undergoing unilateral implantation.
5) Simultaneous implantation and narrower interval between sequential implants were both associated with improved language scores

Study on QOL in Adults
Bichey, 2008

1) Prospective case-control study on 23 bilateral cochlear implant patients
2) All postlingually deafened, severe to profound hearing loss bilaterally
3) Data gathered before first implant, before second, and most recent, using validated Ontario Healthy Utility Index measuring 8 domains of quality of life
4) Cost per QALY $17,832 for first implant. Differential of second is $7112.
5) Greatest improvement is after first cochlear implant, but continue to have improvement in QOL after second implant.

Other Payers
Washington state Medicaid

Cochlear implantation is only covered for children 20 years of age and younger.
It is not covered for adults.
Bilateral cochlear implantation is not covered, only unilateral.

Aetna, 2012

Aetna considers uniaural (monaural) or binaural (bilateral) cochlear implantation a medically necessary prosthetic for adults aged 18 years and older with bilateral, pre- or post-linguistic, sensorineural, moderate-to-profound hearing impairment who meet *both* of the following criteria:

1. Member has bilateral severe to profound sensorineural hearing loss determined by a pure tone average of 70 dB or greater at 500 Hz, 1000 Hz, and 2000 Hz; *and*
2. Member has limited benefit from appropriately fitted binaural hearing aids. Limited benefit from amplification is defined by test scores of 40 % correct or less in best-aided listening condition on open-set sentence cognition (e.g., Central Institute for the Deaf (CID) sentences, Hearing in Noise Test sentences (HINT), and consonant-nucleus-consonant (CNC) test.

Aetna considers uniaural (monaural) or binaural (bilateral) cochlear implantation a medically necessary prosthetic for children 12 months of age or older with bilateral sensorineural hearing impairment who meet *all* of the following criteria:

1. Child has profound, bilateral sensorineural hearing loss determined by a pure tone average of 90 dB or greater at 500, 1000 and 2000 Hz; ***and***
2. Child has limited benefit from appropriately fitted binaural hearing aids. For children 4 years of age or younger, limited benefit is defined as failure to reach developmentally appropriate auditory milestones measured using the Infant-Toddler Meaningful Auditory Integration Scale, the Meaningful Auditory Integration Scale, or the Early Speech Perception test, or less than 20 % correct on open-set word recognition test (Multisyllabic Lexical Neighborhood Test) in conjunction with appropriate amplification and participation in intensive aural habilitation over a 3 to 6 month period. For children older than 4 years of age, limited benefit is defined as less than 12 % correct on the Phonetically Balanced-Kindergarten Test, or less than 30 % correct on the Hearing in Noise Test for children, the open-set Multi-syllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending on the child's cognitive ability and linguistic skills; ***and***
3. A 3- to 6-month hearing aid trial has been undertaken by a child without previous experience with hearing aids. Note: When there is radiological evidence of cochlear ossification, this requirement may be waived at Aetna's discretion.

The following additional medical necessity criteria must also be met for uniaural (monaural) or binaural (bilateral) cochlear implantation in adults and children:

1. The member must be enrolled in an educational program that supports listening and speaking with aided hearing; ***and***
2. The member must have had an assessment by an audiologist and from an otolaryngologist experienced in this procedure indicating the likelihood of success with this device; ***and***
3. The member must have no medical contraindications to cochlear implantation (e.g., cochlear aplasia, active middle ear infection); ***and***

The member must have arrangements for appropriate follow-up care including the long-term speech therapy required to take full advantage of this device. (Note: Particular plans may place limits on benefits for speech therapy services. Please consult plan documents for details).

CIGNA, 2012

A) Cigna covers a unilateral or bilateral cochlear implant as medically necessary for an individual with bilateral sensorineural hearing loss when there is reasonable expectation that a significant benefit will be achieved from the device and when the following age-specific criteria are met:
   (i) For an adult (age 18 years or older) with BOTH of the following: ❑ bilateral, severe-to-profound sensorineural hearing loss determined by a pure-tone average of 70 dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz ❑ limited or no benefit from appropriately fitted hearing aids

(ii) For a child (age 12 months to 17 years, 11 months) with BOTH of the following:
- profound, bilateral sensorineural hearing loss with thresholds of 90 dB or greater at 1000 Hz
- limited or no benefit from a three-month trial of appropriately fitted binaural hearing aids

B) Cigna covers a second cochlear implant in the contralateral (opposite) ear as medically necessary in an individual with an existing unilateral cochlear implant when the hearing aid in the contralateral ear produces limited or no benefit.

C) Cigna covers the replacement of an existing cochlear implant as medically necessary when EITHER of the following criteria is met:
   (i) currently used component is no longer functional and cannot be repaired
   (ii) currently used component renders the implant recipient unable to adequately and/or safely perform his/her age-appropriate activities of daily living

D) Cigna does not cover upgrading of a cochlear implant system or component (e.g., upgrading processor from body-worn to behind-the-ear, upgrading from single- to multi-channel electrodes) of an existing, properly functioning cochlear implant because it is considered not medically necessary.

E) Cigna does not cover a cochlear implant for the treatment of tinnitus in an individual who does not also have profound or severe sensorineural deafness/hearing loss warranting the need for cochlear implantation because such use is considered experimental, investigational or unproven.

Cost: Reimbursement for CPT code 69930 as $21,332.44. The total estimated cost for bilateral cochlear implants in the US is estimated to be around $60,000. The lifetime costs of services, special education, and adaptation related to a child that is deaf before age three, are more than $1 million. Cochlear implants may only partially mitigate the lifetime costs of ongoing significant hearing loss.

For DMAP claims, about 20% are done sequentially, virtually all within a year of the first one.

Summary

There is limited quality data to support that bilateral cochlear implants improve ability to localize sound and speech perception. Most studies do not evaluate patient-oriented outcomes. Currently, DMAP is allowing coverage of bilateral cochlear implants. Simultaneous rather than sequential implantation appears to have more benefit. However, the language of preferring simultaneous to sequential may have operationalization issues however, as some local institutions prefer sequential implants, and sometimes the implants occur many years apart.

Recommendations:

Modify guideline notes 31 and 49 as follows:

GUIDELINE NOTE 31, COCHLEAR IMPLANTATION, AGE 5 AND UNDER

Line 298

Children will be considered candidates for cochlear implants if the following criteria are met:

A) Profound sensorineural hearing loss in both ears (defined as 91dB hearing loss or greater at 500, 1000 and 2000 Hz)
B) Child has reached the age of 1
C) Receive little or no useful benefit from hearing aids
D) No medical contraindications
E) High motivation and appropriate expectations (both child, when appropriate, and family)

Bilateral cochlear implants are covered. Simultaneous implantation appears to be more cost-effective than sequential implantation.

GUIDELINE NOTE 49, COCHLEAR IMPLANTS, OVER AGE 5

Line 491

Children will be considered candidates for cochlear implants if the following criteria are met:

1) Profound sensorineural hearing loss in both ears (defined as 91dB hearing loss or greater at 500, 1000 and 2000 Hz)
2) Receive little or no useful benefit from hearing aids
3) No medical contraindications
4) High motivation and appropriate expectations (both child, when appropriate, and family)

Postlinguistic adults will be considered candidates for cochlear implants if the following criteria are met:

1) Severe to profound sensorineural hearing loss in both ears (defined as 71dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz)
2) Hearing loss acquired after learning oral speech and language development (postlinguistic hearing loss)
3) Receive limited benefit from appropriately fit hearing aids; i.e., scores of 40% or less on sentence recognition test in the best-aided listening condition
4) No medical contraindications

Prelinguistic adults will be considered candidates for cochlear implants if the following criteria are met:

1) Profound sensorineural hearing loss in both ears (defined as 91dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz)
2) Hearing loss acquired before learning oral speech and language development (prelinguistic hearing loss)

3) Receive no benefit from hearing aids
4) No medical contraindications
5) A desire to be a part of the hearing world

Bilateral cochlear implants are covered. Simultaneous implantation appears to be more cost-effective than sequential implantation.

ARTICLE

Effect of Pediatric Bilateral Cochlear Implantation on Language Development

Tinne Boons, MA; Jan P. L. Brokx, PhD; Johan H. M. Frijns, MD, PhD; Louis Peeraer, PhD; Birgit Philips, MA; Anneke Vermeulen, PhD; Jan Wouters, PhD; Astrid van Wieringen, PhD

Objective: To examine spoken language outcomes in children undergoing bilateral cochlear implantation compared with matched peers undergoing unilateral implantation.

Design: Case-control, frequency-matched, retrospective cross-sectional multicenter study.

Setting: Two Belgian and 3 Dutch cochlear implantation centers.

Participants: Twenty-five children with 1 cochlear implant matched with 25 children with 2 cochlear implants selected from a retrospective sample of 288 children who underwent cochlear implantation before 5 years of age.

Intervention: Cochlear implantation.

Main Outcome Measures: Performance on measures of spoken language comprehension and expression (Reynell Developmental Language Scales and Schlichting Expressive Language Test).

Results: On the receptive language tests (mean difference [95% CI], 9.4 [0.3-18.6]) and expressive language tests (15.7 [5.9-25.4] and 9.7 [1.5-17.9]), children undergoing bilateral implantation performed significantly better than those undergoing unilateral implantation. Because the 2 groups were matched with great care on 10 auditory, child, and environmental factors, the difference in performance can be mainly attributed to the bilateral implantation. A shorter interval between both implantations was related to higher standard scores. Children undergoing 2 simultaneous cochlear implantations performed better on the expressive Word Development Test than did children undergoing 2 sequential cochlear implantations.

Conclusions: The use of bilateral cochlear implants is associated with better spoken language learning. The interval between the first and second implantation correlates negatively with language scores. On expressive language development, we find an advantage for simultaneous compared with sequential implantation.

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Currently, more than half the profoundly deaf children in the United States are treated with cochlear implants.[1] Cochlear implants consist of an externally worn microphone and a microprocessor that extracts intensity, frequency, and timing cues from acoustic signals. The system transforms these acoustic cues into an electrical code. Internally, a surgically placed receiver transmits the code to an implanted electrode array that stimulates surviving auditory neurons.

For editorial comment see page 93

Several studies have shown that a second cochlear implant in children has a positive effect on auditory development. Children undergoing bilateral implantation demonstrate improved lateralization[2,3] and localization[2,4,5] skills using both implants compared with using only the first or the second implant. Besides a benefit in localization skills, it has been shown that bilateral implantation induces enhanced speech recognition. Most children achieve better speech recognition scores in quiet[6,7] and in noise[3,8,9] using both cochlear implants instead of one. Moreover, the advantages are greater in children with a limited interimplantation interval.[10]

Improved localization and speech recognition skills enhance the ability to perceive speech in more challenging listening environments, such as noisy classrooms and family gatherings. This improved speech perception could facilitate the ability to pick up language in everyday life. At this time, evidence on the long-term effect of bilateral cochlear implantation on language development is lacking.[11-13] This is partly because individual cochlear implantation centers have too few children undergoing the procedure to control for other variables that may influence language outcomes.

Cervicobrachial syndrome

Question: Should cervicobrachial syndrome (ICD-9 723.3) remain on a funded line or be moved to the same priority line as other neck pain conditions?

Question source: Dr. John Sattenspiel, OHP medical director

Issue: Cervicobrachial syndrome (ICD-9 723.3) currently appears on line 441 PERIPHERAL NERVE ENTRAPMENT. Other neck pain syndromes, such as 723.1 (Cervicalgia), 723.8 (Other syndromes affecting cervical region), 723.9 (Unspecified musculoskeletal disorders and symptoms referable to neck), and 847.0 (Sprain of neck), are located on line 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT.

From http://www.mdguidelines.com/cervicobrachial-syndrome

> Cervicobrachial syndrome is a nonspecific term describing some combination of pain, numbness, weakness, and swelling in the region of the neck and shoulder. These cases included the rare conditions of objectively verifiable vascular compression or neurologic compression due to thoracic outlet syndrome, and the common condition of objectively unexplainable similar symptoms. The term "cervicobrachial syndrome" should therefore denote a collection of neck and arm symptoms for which there is no known cause. If a particular patient can be proven to have cervical radiculopathy or vascular compression in the thoracic outlet, then the specific and objectively documented diagnosis should be used. The term "cervicobrachial syndrome" is used by some physicians to describe symptoms they suspect come from cervical nerve root irritation that cannot be documented, whereas other physicians reserve the term for patients whose symptoms may come from undocumentable thoracic outlet syndrome. The definition of "cervicobrachial syndrome" is probably unique to the doctor who uses the term. It may be that an alternate, objectively documentable diagnosis is present, but most often the diagnosis of "cervicobrachial syndrome" refers to symptoms for which there is no proven diagnosis.

Recommendation:

1) Move 723.3 (cervicobrachial syndrome) from line 441 PERIPHERAL NERVE ENTRAPMENT to line 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT

Chronic Pelvic Inflammatory Conditions

Question: where should chronic pelvic inflammatory conditions be located on the Prioritized List?

Question source: Don Thieman, MD, OHP Medical Director

Issue: Currently, a series of chronic pelvic inflammatory conditions are located on line 56 ACUTE PELVIC INFLAMMATORY DISEASE. A similar diagnosis (614.1 Chronic salpingitis and oophoritis) is located on line 552 PELVIC PAIN SYNDROME, DYSPAREUNIA. The HERC has been asked to review placement of the chronic pelvic inflammatory conditions. These conditions were reviewed as part of the OB/Gyn ICD-10 review process, and no changes were made to their placement.

From Dr. Thieman

> We need to know that inclusion of codes like 615.1 (for chronic endometritis) and 614.4 (for chronic PID) in apparent ATL[above the line] pairs for surgery, in Line 56 "Acute Pelvic Inflammatory Disease", which seems by title to clearly NOT intend this, is an error; or if the title is the "error" and it is truly intended to cover surgery for these codes (without any accompanying Guideline Note). We have an instant case where the gynecologist submitted endometritis in someone with no active clinical findings ("chronic" at best; historical most likely) in a request for hysterectomy where the only other diagnosis is menorrhagia with menstrual pain, without anemia, so a clear denial unless the Line 56 issue is an unwelcome surprise.

Evidence

Chronic endometritis and chronic pelvic inflammatory disease are listed in various literature sources as possible causes of chronic pelvic pain. Multiple articles discussed treatment of acute pelvic inflammatory disease, but treatment of chronic disease was usually discussed with treatment of other chronic pelvic pain conditions.

Expert Input:

Michelle Berlin, MD, OHSU OB/Gyn

> Chronic endometritis can present as unexpected/irregular vaginal bleeding – if no other cause of such bleeding is found, some folks do endometrial biopsy and if evidence of infection found then treat with antibiotics. I would agree w/this management. On the other hand chronic PID is more characterized by pain due to adhesions etc. In other words, chronic PID does not tend to manifest as infection per se but as signs/symptoms of sequelae of PID.
>
> Dr. Berlin assisted with the recommended line placements in the tables below.

Recommendations:

1) Move ICD-9 and ICD-10 codes specifying chronic conditions to line 552 PELVIC PAIN SYNDROME, DYSPAREUNIA (see following tables)
2) Change the name of line 552 to CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA
3) Add ICD-9 codes which could be used for acute or chronic disease to line 552 and keep on line 56 ACUTE PELVIC INFLAMMATORY DISEASE (see following tables)
    a. Add the following guideline to specify that chronic disease is located on the lower line

GUIDELINE NOTE XXX CHRONIC PELVIC INFLAMMATORY CONDITIONS
Lines 56, 552
Chronic pelvic inflammatory conditions (ICD-9 614.2, 614.4, 614.5, 614.8, 614.9, 615.9) are included on the lower line only; acute conditions are included on the upper line.

GUIDELINE NOTE XXX CHRONIC PELVIC INFLAMMATORY CONDITIONS
Lines 56, 552
Chronic pelvic inflammatory conditions (ICD-10 N70.91-N70.93, N71.9, N73.2, N73.4, N73.5, N73.8, N73.9, N74) are included on the lower line only; acute conditions are included on the upper line.

Chronic Pelvic Inflammatory Conditions

ICD-9 Code	Code Description	Current Line	Recommended Line(s)	Notes/Comments
614.1	Chronic salpingitis and oophoritis	**552** PELVIC PAIN SYNDROME, DYSPAREUNIA	**552**	
614.2	Salpingitis and oophoritis not specified as acute, subacute, or chronic	**56** ACUTE PELVIC INFLAMMATORY DISEASE	**56, 552**	Includes tubo-ovarian abscess, salpingitis, oophoritis
614.3	Acute parametritis and pelvic cellulitis	**56**	**56**	Pelvic cellulitis is a synonym for parametritis
614.4	Chronic or unspecified parametritis and pelvic cellulitis	**56**	**56, 552**	Includes abscess of the broad ligament, parametrim or pelvis, chronic PID
614.5	Acute or unspecified pelvic peritonitis, female	**56**	**56, 552**	
614.6	Pelvic peritoneal adhesions, female (postoperative) (postinfection)	**552**	**552**	
614.7	Other chronic pelvic peritonitis, female	**56**	**552**	No sub-diagnoses listed
614.8	Other specified inflammatory disease of female pelvic organs and tissues	**56**	**56, 552**	No sub-diagnoses listed
614.9	Unspecified inflammatory disease of female pelvic organs and tissues	**56**	**56, 552**	Includes PID NOS and PID
615.0	Acute inflammatory diseases of uterus, except cervix	**56**	**56**	
615.1	Chronic inflammatory diseases of uterus, except cervix	**56**	**552**	
615.9	Unspecified inflammatory disease of uterus	**56**	**56, 552**	Includes endometritis, myometritis, myometra, uterine abscess

Chronic Pelvic Inflammatory Conditions

ICD-10 Code	Code Description	Current Line	Recommended Line(s)	Notes/Comments
N70.0x	Acute salpingitis and/or oophoritis	**56**	**56**	
N70.1x	Chronic salpingitis and/or oophoritis	**552**	**552**	
N70.91	Salpingitis, unspecified	**56**	**56, 552**	
N70.92	Oophoritis, unspecified	**56**	**56, 552**	
N70.93	Salpingitis and oophoritis, unspecified	**56**	**56, 552**	
N71.0	Acute inflammatory disease of uterus	**56**	**56**	
N71.1	Chronic inflammatory disease of uterus	**56**	**552**	
N71.9	Inflammatory disease of uterus, unspecified	**56**	**56, 552**	
N73.0	Acute parametritis and pelvic cellulitis	**56**	**56**	
N73.1	Chronic parametritis and pelvic cellulitis	**56**	**552**	
N73.2	Unspecified parametritis and pelvic cellulitis	**56**	**56, 552**	
N73.3	Female acute pelvic peritonitis	**56**	**56**	
N73.4	Female chronic pelvic peritonitis	**56**	**56, 552**	
N73.5	Female pelvic peritonitis, unspecified	**56**	**56, 552**	
N73.6	Female pelvic peritoneal adhesions (postinfective)	**552**	**552**	
N73.8	Other specified female pelvic inflammatory diseases	**56**	**56, 552**	
N73.9	Female pelvic inflammatory disease, unspecified	**56**	**56, 552**	
N74	Female pelvic inflammatory disorders in diseases classified elsewhere	**56**	**56, 552**	

Mental Health Codes on Back Pain Lines

Question: should certain mental health codes continue to be on the low back pain lines (Lines 400 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT and 562)?

Question source: DMAP

Issue: Pscyhotherapy CPT codes were recently added to the low back pain lines (Line 400 and 562) to allow cognitive behavioral therapy for low back pain conditions. Health and behavior assessment codes (CPT 96150-154) are already on this line. Guideline Note 94 was also recently added to the List to link evaluation and treatment of low back pain diagnoses to the HERC approved coverage guidance for this condition.

From DMAP:

> It has come to my attention that there are some coding issues with the placement of CPT codes 90785, 90832-90838, and 90840 on Lines 400 and 562. Those CPT codes are for the treatment of mental illness and behavioral disturbances using a mental illness diagnosis. The CPT codes 96150-96154 which are included on line 400 and referenced in Guideline Note 1 are used to identify the psychological, behavioral, emotional, cognitive, and social factors important to the prevention, treatment, or management of physical health problems. Using the link referenced in Guideline Note 1, I find CMSs *Code and Billing Guidelines for Health and Behavior Assessment/ Intervention*. This document defines correct coding and use of the codes 96150-96154. Cognitive behavior therapy can be defined using the code set 96154-96154 (in the absence of a mental illness diagnosis) and supports the EBGS's Coverage Guidance for Non-Pharmacologic Management of Low Back Pain. Provider types billing with the CPT codes 90785, 90832-90838, and 90840 would need to use a mental illness diagnosis per correct coding instructions/ conventions. Including CPT codes 90785, 90832-90838, and 90840 on Lines 400 and 562 is confusing and will lead to coding errors and inaccuracies.
>
> I am respectfully requesting:
> 1) Removal of the Psychotherapy CPT codes 90785, 90832-90838, and 90840 from line 400 and 562
> 2) Consider placing the code set 96150-96154 on line 562
> 3) Revision of the Coding Specification for line 400 and line 562 or removing it all together as both lines reference Guideline Note 94. Or replace " Cognitive behavioral therapy (90785-90840) only pairs on Line 400 with the low back pain diagnoses (344.60, 722.1, 722.2, 727.7, 724.4)" with "Health and Behavior Assessment Intervention Codes (96150-96154) are included on this line as defined in Guideline Note 94 for the Non-Pharmacologic Management of Low Back Pain (344.60, 722.1, 722.2, 727.7, 724.4)" and "… on Line 562 with the low back pain diagnoses (720.2, 721.3, 721.7, 721.8, 721.90, 722.1, 722.2, 722.32, 722.39, 722.5, 722.6, 722.8, 722.9, 724.1, 724,2, 724.5-724.9, 739.2-739.4, 847.1-847.9)".
>
> Also of note: The link referenced in Guideline Note 1 for the CMS document related to Health and behavior assessment and interventions indicates a date of 2/1/2006. The one I found navigating from that link and using search for Health and Behavior led me to a more

current pdf document dated 2010. Not sure if there should be an update to this reference in the Guideline.

Current Prioritized List Information:
Coding specification on line 400
"Cognitive behavioral therapy (90785-90840) only pairs on line 400 with the low back pain diagnoses (344.60, 722.1, 722.2, 727.7, 724.4)."

Coding specification on line 562
"Cognitive behavioral therapy (90785-90840) only pairs on line 562 with the low back pain diagnoses (720.2, 721.3, 721.7, 721.8, 721.90, 722.1, 722.2, 722.32, 722.39, 722.5, 722.6, 722.8, 722.9, 724.1, 724,2, 724.5-724.9, 739.2-739.4, 847.1-847.9)."

GUIDELINE NOTE 1, HEALTH AND BEHAVIOR ASSESSMENT/INTERVENTION
Lines 1,6,8,10-18,20-22,25,26,28,29,33-37,39-42,46,47,50,52,53,55,57,62,64,66,67,69,71,74, 76,79,80,82,84,85,87,92,94,96,98,100-103,105,108-111,113,115,119, 122-124, 128, 134, 135,137,138,140,141,144,146,147,149-151,158,159,164-169,173,179,181-183,185,190, 191, 193,195-197,199,201,202,205,207-210,218,220,221,224,227-229,233,235-238,244,246,249, 250,252-256,265-268,271-279,285,287,288,290,292,293,302,304,306,310-314,320,326,331, 333,334,338-342,352,354,356,357,360,366,370,371,376,377,387,394,400,407,410,421-423,426,432, 434, 435,439,442,444,446,447,459,462,466,470-472,478,489,491,506
Health and behavior assessment and interventions (CPT codes 96150-96154) are included on these lines when provided subject to the Centers for Medicare and Medicaid (CMS) guidelines dated 2/1/06 located at:
http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=13492&lcd_version=48&basket=lcd%3A13492%3A48%3AHEALTH+AND+BEHAVIOR+ASSESSMENT%2FINTERVENTION%3ACarrier%3ANHIC%7C%7C+Corp%2E+%2831142%29%3A.
In addition, Managed Care Organizations may authorize employees of organizations holding certificates or letters of approval from DHS and a Medicaid vendor number to deliver these services (i.e., not delivering services as an independent practitioner).

GUIDELINE NOTE 94, EVALUATION AND MANAGEMENT OF LOW BACK PAIN
Lines 400,562
Procedures for the evaluation and management of low back pain are included on these lines when provided subject to the State of Oregon Evidence-based Clinical Guidelines dated 10/2011 located at:
http://www.oregon.gov/OHA/OHPR/HERC/Evidence-Based-Guidelines.shtml

Further information:

1) Research into coding guidelines for cognitive behavioral therapy (CBT) indicate that the health and behavior assessment codes CPT 96150 and 96152 should be used for assessment and treatment of the psychological factors affecting a physical health condition such as low back pain.
2) The current line to the CMS guideline in Guideline Note 1 does not work. An updated guideline exists.

HERC Staff Recommendations:

1) Remove psychotherapy CPT codes (CPT 90785, 90832-90838, and 90840) from line 400 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT and 562 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT
2) Keep the health and behavior assessment codes (CPT 96150-96154) on line 400
3) Add CPT 96150-96154 to line 562
4) Remove the coding specifications for line 400 and 562
    a. The use of the health and behavior assessment codes will be determined by Guideline Note 94 which is already referenced on these lines
5) Change Guideline Note 1 to reflect the updated CMS link as shown below

GUIDELINE NOTE 1, HEALTH AND BEHAVIOR ASSESSMENT/INTERVENTION

Lines 1,6,8,10-18,20-22,25,26,28,29,33-37,39-42,46,47,50,52,53,55,57,62,64,66,67,69,71,74, 76,79,80,82,84,85,87,92,94,96,98,100-103,105,108-111,113,115,119, 122-124, 128, 134, 135,137,138,140,141,144,146,147,149-151,158,159,164-169,173,179,181-183,185,190, 191, 193,195-197,199,201,202,205,207-210,218,220,221,224,227-229,233,235-238,244,246,249, 250,252-256,265-268,271-279,285,287,288,290,292,293,302,304,306,310-314,320,326,331, 333,334,338-342,352,354,356,357,360,366,370,371,376,377,387,394,400,407,410,421-423,426,432, 434, 435,439,442,444,446,447,459,462,466,470-472,478,489,491,506

Health and behavior assessment and interventions (CPT codes 96150-96154) are included on these lines when provided subject to the Centers for Medicare and Medicaid (CMS) guidelines dated 2/1/06 located at:

~~**http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=13492&lcd_version=48&basket=lcd%3A13492%3A48%3AHEALTH+AND+BEHAVIOR+ASSESSMENT%2FINTERVENTION%3ACarrier%3ANHIC%7C%7C+Corp%2E+%2831142%29%3A.**~~

http://downloads.cms.gov/medicare-coverage-database/lcd_attachments/30514_1/L30514_031610_cbg.pdf

In addition, Managed Care Organizations may authorize employees of organizations holding certificates or letters of approval from DHS and a Medicaid vendor number to deliver these services (i.e., not delivering services as an independent practitioner).

Coding and Billing Guidelines

Contractor Name
Wisconsin Physicians Service (WPS)

Contractor Number
00951, 00952, 00953, 00954
05101, 05201, 05301, 05401,
05102, 05202, 05302,
05402, 52280

Contractor Type
Carrier
Fiscal Intermediary (FI)
MAC – A
MAC – B

Article Type
LCD Companion Article

Article Title
PSYCH-015 - Health and Behavior Assessment/Intervention

Effective Date
03/16/2010

Health and Behavior Assessment
Health and behavior assessment procedures are used to identify the psychological, behavior, emotional, cognitive, and social factors important to the prevention, treatment, or management of physical health problems.

The Health and Behavioral Assessment codes, CPT 96150-96154, are used to describe services that are intended to assess factors that may affect the recovery or progression of a diagnosed physical health problem or illness. Specifically this would include assessment and treatment for biopsychosocial factors that do not directly treat the illness and the focus is not on mental health issues. If the beneficiary has a mental health diagnosis, the 96150 – 96154 codes would not be appropriate. In addition, these services do not represent preventive medicine counseling and risk factors reduction interventions.

CMS National Coverage Policy:
Title XVIII of the Social Security Act section 1862 (a)(1)(A). This section allows coverage and payment of those services that are considered medically reasonable and necessary.
Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services p
Title XVIII of the Social Security Act section §1833 (c) and §1833 (e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.'
Code of Federal Register
CFR Title 42, Part 410.73(b)(1) [Revised as of October 1, 2004][CITE: 42CFR410.73]
CMS) of the Act and in §2470ff
(1) *Definition.* ''Clinical social worker services'' means, except as specified in paragraph (b)(2) of this section, the services of a clinical social worker furnished for the diagnosis and treatment of mental illness that the clinical social worker is legally authorized to perform under State law (or

the State regulatory mechanism provided by State law) of the State in which the services are performed. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

Coding Guidelines

1. CPT codes 96150 - 96154 represent services offered to beneficiary who present with established illness or symptoms, the purpose of the assessment is not for the diagnosis or treatment of mental illness, and may benefit for evaluations that focus on the biopsychosocial factor related to the beneficiary's physical health status
2. Physician's must bill health and behavior assessment and/or intervention services with an Evaluation and Management or preventive Medicine service codes.
3. Medical records must document the specific underlying medical problem
4. Health and behavior assessment normally will be performed in an office or facility setting.
5. Health and behavior assessment codes may not be used for physician (example: medical doctor, nurse practitioner, physician assistant, clinical nurse practitioner) or clinical social worker services.
6. CPT codes 96150 – 96154 are to be billed as one service for each 15 minute of face-to-face contact with the beneficiary(s).

*7. When more than four CPT codes 96150 are submitted by a provider/group the additional services will be denied. If a redetermination is requested, documentation showing the medical necessity of the additional time must be submitted.

CPT Codes

96150	Health and behavior assessment (eg, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment
96151	Health and behavior assessment (eg, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; re-assessment
96152	Health and behavior intervention, each 15 minutes, face-to-face; individual
96153	Health and behavior intervention, each 15 minutes, face-to-face; group (2 or more patients)
96154	Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)

Diagnoses that Support Medical Necessity

Medical diagnoses only

Reasons for Denial

1. Beneficiaries who do not have specific underlining medical condition.
2. Services for preventive medicine counseling and/or risk factor reduction intervention.
3. Services to beneficiaries who require psychiatric services (services should be billed with CPT codes 90801 – 90899).
4. Evaluation and Management services, including Preventive Medicine, Individual Counseling codes 99401 – 99404, and Preventive Medicine, Group Counseling codes 99411 – 99412 billed on the same day as 96150 – 96154.

5. Health and behavior assessment and/or intervention performed by a physician, clinical nurse specialist, nurse practitioner, physician assistant. These services should be billed using the appropriate evaluation and management CPT codes.
6. Health and behavior assessment and/or intervention performed by a clinical social worker. Per CFR Title 42, Part 410.73(b)(1) the services of a clinical social worker are limited to the diagnosis and treatment of mental illness.
7. Health and behavior assessment and/or intervention performed by physical therapist, or occupational therapist.
8. Smoking cessation; (use CPT codes G0375 - G0376).

Additional information may be found at

http://www.cms.hhs.gov/manuals/14_car/3b5111.asp#_1_5 define SW ect
http://www.cms.hhs.gov/manuals/pm_trans/R1660B3.pdf

Original Effective Date

03/16/2010,

Revision History Number/Explanation

02/01/2010, one, merge of legacy LCD into J-5 and Legacy LCD, this LCD replaces all other previous LCDs on this subject including L21749, L21751, L21753, and L21755;

Publication Date

02/01/2010,

Section 9

Straightforward Items

Straightforward Issues—March, 2013

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
32663	Thoracoscopy, surgical; with lobectomy (single lobe)	**204** CONGENITAL CYSTIC LUNG - MILD AND MODERATE	An OHP Medical Director requested that 32663 be added to line 204, to pair with congenital cystic lung. Currently, 32663 is found only on line 677 CONGENITAL CYSTIC LUNG – SEVERE. The open equivalent, 32480 (Removal of lung, other than pneumonectomy; single lobe (lobectomy)) is located on line 204. Similar thorascopic codes are already present on line 204 (i.e. 32670 thorascopic bilobectomy).	Add 32663 to line 204
92250	Fundus photography with interpretation and report	**106** DIABETIC AND OTHER RETINOPATHY **147** OPPORTUNISTIC INFECTIONS IN IMMUNOCOMPROMISED HOSTS; CANDIDIASIS OF STOMA; PERSONS RECEIVING CONTINUOUS ANTIBIOTIC THERAPY **354** COCCIDIOIDOMYCOSIS, HISTOPLASMOSIS, BLASTOMYCOTIC INFECTION, OPPORTUNISTIC AND OTHER MYCOSES	DMAP is requesting that 92250 be added to line 354 to pair with 115.92 (Unspecified Histoplasmosis retinitis). Currently, 92250 is on more than 40 lines. The only effective treatment for histoplasmosis retinitis is photocoagulation (CPT 67210)—there is no treatment for the underlying infection.. The majority of retinitis diagnosis codes are on line 106, with a full range of treatment codes.	Add 115.92 to line 106 Remove 115.92 from lines 147 and 354

Straightforward Issues—March, 2013

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
77421	Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy	**287** CANCER OF BLADDER AND URETER	DMAP is requesting that 77421 be added to line 287 to pair with 188.8 (Malignant neoplasm of other specified sites of bladder). 77421 currently pairs on multiple lines; other radiation therapy codes are on line 287.	Add 77421 to line 287
57505	Endocervical curettage (not done as part of a dilation and curettage)	**144** CANCER OF CERVIX	DMAP is requesting that 57505 be added to line 144 to pair with 180.0 (Malignant neoplasm of endocervix). 57505 is currently on line 31, DYSPLASIA OF CERVIX AND CERVICAL CARCINOMA IN SITU, CERVICAL CONDYLOMA.	Add 57505 to line 144
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications	**340** CANCER OF LIVER **356** CANCER OF PROSTATE GLAND	DMAP is requesting that 77301 be added to line 356 to pair with 185 (Malignant neoplasm of prostate) and to line 340 to pair with 155.0 (Malignant neoplasm of liver, primary). 77301 is currently on more than 20 lines. Both line 340 and 356 have multiple radiation CPT codes.	Add 77301 to lines 340 and 356.
61548	Hypophysectomy or excision of pituitary tumor, transnasal or transseptal approach, nonstereotactic	**46** PANHYPOPITUITARISM, IATROGENIC AND OTHER PITUITARY DISORDERS **162** BENIGN NEOPLASM OF PITUITARY GLAND	DMAP is requesting that 61548 be paired with 253.8 (Other disorders of the pituitary & other syndromes of diencephalon-hypophyseal origin). 61548 is currently on lines 137, 162, 201, 371, 622. Line 46 is a medical line only. 253.8 is used for various benign diagnoses.	Add 253.8 to line 162

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
67412	Orbitotomy without bone flap (frontal or transconjunctival approach); with removal of lesion	**124** CANCER OF EYE AND ORBIT **208** CANCER OF BONES	DMAP is requesting that 67412 be added to line 124 to pair with 238.8 (Neoplasm of uncertain behavior of other specified sites). 67412 is currently on lines 147 and 354. Similar code 67414 is on line 124. DMAP is also requesting that 67412 be added to line 208 to pair with 238.0 (Neoplasm of uncertain behavior of bone & articular cartilage).	Add 67412 to lines 124 and 208
52214	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands	**228** CANCER OF KIDNEY AND OTHER URINARY ORGANS **287** CANCER OF BLADDER AND URETER **291** UROLOGIC INFECTIONS	DMAP is requesting that 52214 be added to line 287 to pair with 188.9 (Malignant neoplasm of bladder, part unspecified) and 233.7 (Carcinoma in situ of bladder), to line 228 to pair with 236.99 (Neoplasm of uncertain behavior of other & unspecified urinary organs, Other) and to line 291 to pair with 595.81 (Cystitis cystica) and 595.82 (Irradiation cystitis. 52214 is currently on lines 96 and 351. Similar codes 52224-52240 are on lines 228 and 287. No similar codes are on line 291.	Add 52214 to lines 228 and 287 Do not add 52214 to line 291

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
54520 54522 54530 54535	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach Orchiectomy, partial Orchiectomy, radical, for tumor; inguinal approach Orchiectomy, radical, for tumor; with abdominal exploration	**104** UNDESCENDED TESTICLE **261** TORSION OF TESTIS **275** CANCER OF PENIS AND OTHER MALE GENITAL ORGANS	DMAP is requesting review of placement of 54530. This code is currently on lines 104, 123, 261, 356. 54535 is currently found on lines 104, 123, 261. DMAP is requesting that 54530 be added to line 275 to pair with 233.6 (Carcinoma in situ of other and unspecified male genital organs).	Remove 54530 and 54535 from lines 104 and 261. Add 54520-54535 to line 275
		70 SUBSTANCE-INDUCED DELIRIUM	Recently, psychotherapy codes 90785, 90832-90838, and 90840 were added to Line 70. DMAP is requesting that the line treatment description be changed from MEDICAL THERAPY to MEDICAL / PSYCHOTHERAPY. This would be consistent with the treatment descriptions on lines 32 and 68.	Change treatment description for line 70 to MEDICAL / PSYCHOTHERAPY
99241-99245	Office consultation for a new or established patient		CMS no longer covers consultation codes and these codes have been removed from the DMAP fee schedule. Providers are asked to use E&M codes instead. The consultation codes are currently on >600 lines on the List.	Remove 99241-99245 from all lines on the Prioritized List Advise DMAP to place 99241-99245 on the Excluded List

Straightforward Issues—March, 2013

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
41512	Tongue base suspension, permanent suture technique	**171** LEUKOPLAKIA AND CARCINOMA IN SITU OF ORAL MUCOSA, INCLUDING TONGUE	41512 was added to the Excluded List at the December, 2008 HSC meeting. However, it was mistakenly also added to line 171 and has appeared on that line since 2009.	Remove 41512 from line 171 Keep 41512 on Excluded List
56441	Lysis of labial adhesions	**380** CONGENITAL ABSENCE OF VAGINA **658** NONINFLAMMATORY DISORDERS OF CERVIX; HYPERTROPHY OF LABIA	Dr. Chris Kirk requested that 56441 be considered for pairing with 752.49 (Other anomalies of cervix, vagina, and external female genitalia) which includes congenital labial adhesions as a subdiagnosis. Currently, 56441 is on line 587. On further review, 624.8 (Other specified noninflammatory disorders of vulva and perineum) codes for non-congenital labial adhesions. 624.8 is on line 658 and should be paired with this procedure as well.	Add 56441 to lines 380 and 658
62272	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter)	**320** CANCER OF BRAIN AND NERVOUS SYSTEM	DMAP is requesting that 62272 be added to line 320 for use for malignant neoplasms of the CNS. 62272 is on 4 lines, including benign neoplasms of the CNS. Shunt placement is currently on line 320.	Add 62272 to line 320

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
45114 45116	Proctectomy, partial, with anastomosis; abdominal and transsacral approach Proctectomy, partial, with anastomosis; transsacral approach only (Kraske type)	**35** REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE	DMAP is requesting that 45114 be added to line 35 to pair with 555.1 Regional enteritis large intestine. 45114 is currently on lines 111 and 174. Similar CPT procedures 45112, 45113, 45119, 45123 are located on line 35. On review, 45116 is also missing from line 35.	Add 45114 and 45116 to line 35
44130	Enteroenterostomy, anastomosis of intestine, with or without cutaneous enterostomy (separate procedure)	**163** ACUTE VASCULAR INSUFFICIENCY OF INTESTINE	DMAP is requesting that 45130 be added to line 163 to pair with 557.0 (Acute vascular insufficiency of intestine). 44130 is currently on lines 48, 78, 97, 111, 229, 341. Several enterectomy codes are on line 163.	Add 44130 to line 163
59821	Treatment of missed abortion, completed surgically; second trimester	**394** SPONTANEOUS ABORTION	DMAP is requesting that 59821 be added to line 394 to pair with 634.71 Incomplete spontaneous abortion with other specified complications. 59820 (Treatment of missed abortion, completed surgically; first trimester) is on line 394	Add 59821 to line 394
27707	Osteotomy; fibula	**467** MALUNION AND NONUNION OF FRACTURE	DMAP is requesting that 27707 be added to line 467 to pair with 733.82 Nonunion of fracture. 27707 is currently only on line 190 ACUTE OSTEOMYELITIS. Osteotomy of other bones are included on line 467.	Add 27707 to line 467