Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

lixisenatide (Adlyxin)

Notes:

• Quantity Limits: Yes

<u>Initiation (new start) criteria:</u> Non-formulary **lixisenatide (Adlyxin)** will be covered on the prescription drug benefit for when the following criteria are met:

- Diagnosis of Type 2 Diabetes Mellitus
- Intolerance to preferred GLP-1 agonists liraglutide (Victoza) AND injectable semaglutide (Ozempic)
- No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- No personal history of gastroparesis
- On maximally tolerated metformin dose (dose appropriate per renal function) or allergy or intolerance* to metformin (includes both metformin IR and XR)
- And meets <u>one</u> of the following criteria:
 - Inadequate glycemic response on both basal and bolus insulin despite high dose requirements (total daily insulin dose of 1.5 units per kilogram of body weight or more OR greater than 200 units) OR
 - Has experienced recurrent nocturnal hypoglycemia with basal insulin defined as: 3 or more episodes of nocturnal hypoglycemia (BG less than 70 mg/dL) over the preceding 30 days that persists despite basal insulin dose reduction (including decrease in NPH dose and subsequent switch to and dose adjustment of insulin glargine)



^{*} Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment and do not require medication discontinuation

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<u>Criteria for members already taking the medication who have not been reviewed</u> <u>previously (e.g., new members):</u> Non-formulary lixisenatide (Adlyxin) will be covered on the prescription drug benefit for when the following criteria are met:

- Diagnosis of Type 2 Diabetes Mellitus
- Intolerance to preferred GLP-1 agonists liraglutide (Victoza) AND injectable semaglutide (Ozempic)
- No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- No personal history of gastroparesis
- On maximally tolerated metformin dose (dose appropriate per renal function) or allergy or intolerance* to metformin (includes both metformin IR and XR)
- And meets <u>one</u> of the following criteria:
 - Inadequate glycemic response on both basal and bolus insulin despite high dose requirements (total daily insulin dose of 1.5 units per kilogram of body weight or more OR greater than 200 units) OR
 - Has experienced recurrent nocturnal hypoglycemia with basal insulin defined as: 3 or more episodes of nocturnal hypoglycemia (BG less than 70 mg/dL) over the preceding 30 days that persists despite basal insulin dose reduction (including decrease in NPH dose and subsequent switch to and dose adjustment of insulin glargine)



^{*} Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment and do not require medication discontinuation