



Commercial/Healthcare Exchange PA Criteria

Effective: November 2014

Prior Authorization: Non-Preferred GLP-1 inhibitors (Incretin Mimetics)

Products Affected: Adlyxin

Medication/Class Description:

GLP-1 is produced from the proglucagon gene in L-cells of the small intestine and is secreted in response to food intake. GLP-1 binds to specific GLP-1 receptors expressed in various tissues including pancreatic beta cells, pancreatic ducts, gastric mucosa, etc. GLP-1 exerts its main effect by stimulating glucose-dependent insulin release from the pancreatic islets. It has also been shown to slow gastric emptying, inhibit inappropriate post-meal glucagon release, and thereby reduce food intake. Exenatide administration results in decreases in hemoglobin A1c (HbA1c) by approximately 0.5% to 1% (immediate release) or 1.5% to 1.9% (ER). Liraglutide administration results in decreases in hemoglobin A1c by approximately 1%. Due to the effects of GLP-1 on slowed gastric emptying and appetite centers in the brain, therapy with GLP-1 receptor agonists is associated with weight loss, even among patients without significant nausea and vomiting.

Covered Uses: Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

Exclusion Criteria:

Trulicity only:

1. Patients with a personal or family history of medullary thyroid carcinoma (MTC)
2. Patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)

Required Medical Information:

1. Diagnosis
2. History of previous therapy tried/failed
3. Current therapy regimen
4. Hgb A1C value(s)

Age Restrictions: 18 years of age and older

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Other Criteria:

1. Patient has a diagnosis of Type 2 diabetes mellitus; AND
2. Patient has an intolerance to, or treatment failure of one of the following: Cycloset, Acarbose, Glyset, Miglitol, Precose, Fortamet, Glucophage/XR, Glumetza, metformin/ER, Riomet, Oseni, alogliptin-pioglitazone, alogliptin, Januvia, Nesina, Onglyza, Tradjenta, Amaryl, Chlorpropamide, glimepiride, glipizide/XL/ER, Glucotrol/XL, glyburide, Glynase, nateglinide, Prandin, repaglinide, Starlix, tolazamide, tolbutamide, Glyxambi, Qtern, Steglujan, Actoplus Met/XR, Avandamet, pioglitazone-metformin, Duetact, pioglitazone-glimepride, alogliptin-

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metformin, Janumet/XR, Jentadueto/XR, Kazano, Kombiglyze XR, glipizide-metformin, Glucovance, glyburide-metformin, repaglinide-metformin, Actos, Avandia, pioglitazone, Admelog/Solostar, Afrezza, Apidra, Basaglar, Fiasp, Humalog (all), Humulin (all), Insulin lispro, Lantus, Levemir, Myxredlin, Novolin (all), Novolog (all), Toujeo, Tresiba; AND

3. Patient has an intolerance to, or treatment failure of TWO of the following (the below list of drugs may also require step therapy):

- a. Victoza (liraglutide)
- b. Byetta (exenatide)
- c. Bydureon (exenatide)
- d. Ozempic (semaglutide)
- e. Rybelsus (semaglutide)
- f. Trulicity (dulaglutide)

References:

1. Product Information: TRULICITY(R) subcutaneous injection, dulaglutide subcutaneous injection. Eli Lilly and Company (per FDA), Indianapolis, IN, 2018.
2. Product Information: ADLYXIN(TM) subcutaneous injection, lixisenatide subcutaneous injection. sanofi-aventis US LLC (per manufacturer), Bridgewater, NJ, 2016.

Revision History:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	11/2014
2	Policy Update	New Template, removal of preferred products; Addition of second preferred GLP trial; CCI P&T Review History: 11/15, 2/16, 11/16, 2/17, 5/17, 5/18, 5/19 CCI Revision Record: 12/10, 3/12, 11/12, 4/14, 6/14, 11/14, 11/16, 2/17, 5/17, 1/18, 5/18, 5/19	All	12/11/2019

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3	Update	Removed Trulicity from Products affected Added Trulicity to preferred GLP1 trials in Other Criteria	Products Affected Other Criteria	3/2020
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