

Commercial PA Criteria

Effective: May 1, 2024

Prior Authorization: Glucagon-Like Peptide-1 Agonists (GLP-1)

Products Affected:

- Adlyxin® (lixisenatide subcutaneous injection)
- Bydureon® (exenatide extended-release subcutaneous injection)–
- Bydureon BCise® (exenatide extended-release subcutaneous injection)
- Byetta® (exenatide subcutaneous injection)
- Mounjaro (tirzepatide subcutaneous injection)
- Ozempic® (semaglutide subcutaneous injection)
- Rybelsus® (semaglutide tablets)
- Trulicity® (dulaglutide subcutaneous injection)
- Victoza® (liraglutide subcutaneous injection)

Note: Saxenda® (liraglutide subcutaneous injection), Wegovy® (semaglutide subcutaneous injection) and Zepbound™ (tirzepatide SC injection) are indicated for chronic weight management, not diabetes, and are not targeted in this policy. All approvals are provided for the duration noted below.

Medication 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:

1. All of the products are Indicated as adjuncts to diet and exercise to improve glycemic control in adults with type 2 diabetes.
2. Victoza, Trulicity, and Bydureon/Bydureon BCise are additionally indicated for type 2 diabetes in patients \geq 10 years of age.
3. Victoza, Ozempic, and Trulicity also have labeled indications related to cardiovascular (CV) risk reduction in adults with type 2 diabetes.

Exclusion Criteria:

1. Weight loss treatment - The GLP-1 agonists and GLP-1/GIP agonist included in this policy are not FDA-approved for chronic weight management in a patient who is overweight (body mass index [BMI] \geq 27

kg/m²) or obese (BMI ≥ 30 kg/m²) without type 2 diabetes. *Note: If the patient has type 2 diabetes, refer to FDA-Approved Indication.*

2. Type 1 Diabetes Mellitus - None of the GLP-1 agonists are indicated for patients with type 1 diabetes
3. Prediabetes/Diabetes Prevention - GLP-1 agonists are not indicated in a patient with elevated blood glucose who does not have type 2 diabetes.
4. Metabolic Syndrome - The GLP-1 agonists are not indicated in a patient with metabolic syndrome who does not have type 2 diabetes.

Required Medical Information:

1. Diagnosis
2. Hgb A1c value(s)
3. Fasting plasma glucose (FPG)
4. 2-hour plasma glucose (2-h PG)
5. Documentation is required for use of the GLP-1 agonists targeted in this policy as noted in the criteria as [documentation required]. Documentation may include, but is not limited to the patient's medical claims records, chart notes, and/or test results.

Age Restrictions & Automation:

The following automation is applied in this policy:

1. When available, the ICD-10 code for type 2 diabetes, E11, will be used as part of automation to allow approval of the requested medication. The following age automation also applies:
 - **Adlyxin, Byetta, Mounjaro, Ozempic, Rybelsus:** If the patient is < 18 years of age, coverage will be determined by Prior Authorization criteria.
 - **Bydureon, Bydureon BCise, Trulicity, Victoza:** If the patient is < 10 years of age, coverage will be determined by Prior Authorization criteria.

Prescriber Restrictions: None

Coverage Duration: 1 year

Other Criteria:

Initial Approval Criteria – FDA Approved Indication

1. Type 2 Diabetes Mellitus.

Approve for 1 year if the patient meets the following (A **AND** B **OR** A **AND** C):

- A. Patient has a diagnosis of type 2 diabetes confirmed by the history ONE of the following (i, ii, **OR** iii):
 - i. Hemoglobin A_{1c} (HbA_{1c}) ≥ 6.5% **[documentation required]; OR**
 - ii. Fasting plasma glucose (FPG) ≥ 126 mg/dL **[documentation required]; OR**
 - iii. 2-hour plasma glucose (2-h PG) ≥ 200 mg/dL **[documentation required]; AND**
- B. If the request is for Adlyxin, Byetta, Mounjaro, Ozempic, Rybelsus: Approve if the patient is ≥ 18 years of age; **OR**

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- C. If the request is for Bydureon, Bydureon BCise, Trulicity, Victoza: Approve if the patient is ≥ 10 years of age.

References:

1. Adlyxin[®] subcutaneous injection [prescribing information]. Bridgewater, NJ: sanofi-aventis; June 2022.
2. Bydureon[®] subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; December 2022.
3. Bydureon BCise[®] subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; December 2022.
4. Byetta[®] subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; December 2022.
5. Ozempic[®] subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; September 2023.
6. Rybelsus[®] tablets [prescribing information]. Plainsboro, NJ: Novo Nordisk; January 2023.
7. Trulicity[®] subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; November 2022.
8. Victoza[®] subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; July 2023.
9. American Diabetes Association. Standards of medical care in diabetes – 2024. *Diabetes Care*. 2024;47(Suppl 1):S1-S321.
10. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological management of obesity: An endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2015;100(2):342-362.
11. Grunvald E, Shah R, Hernaez R, et al. AGA clinical practice guideline on pharmacological interventions for adults with obesity. *Gastroenterol*. 2022;163:1198-1225.
12. Mounjaro[™] subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; July 2023.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	05/01/2024