Antidiabetics – GLP-1 Agonists

WA.PHAR.122 Effective Date: February 1, 2022

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current publication of the Coordinated Care of Washington, Inc. Preferred Drug List (PDL), please visit: https://pharmacy.envolvehealth.com/content/dam/centene/envolve-pharmacy-solutions/pdfs/PDL/FORMULARY-CoordinatedCare_Washington.pdf

Background:

Glucagon-like peptide 1 (GLP-1) agonists, also called incretin mimetics, are used for the treatment of type 2 diabetes. GLP-1 causes the pancreas to produce more insulin after eating and helps keep blood glucose levels within the normal range. GLP-1 agonists mimic the action of GLP-1 made by the body and can affect glucose control through several mechanisms including enhancement of glucose-dependent insulin secretin, slowed gastric emptying, and reduction of postprandial glucagon and food intake.

Medical necessity

Drug	Medical Necessity
Dulaglutide (**Trulicity)** Exenatide **(Byetta)** Exenatide Extended Release (**Bydureon BCise)** Liraglutide (**Victoza)** Lixisenatide (**Adlyxin)** Semaglutide subcutaneous, tablet (**Ozempic, Rybelsus)** Tirzepatide (**Mounjaro)**	**GLP-1 Agonists** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

Clinical Criteria	
Type 2 Diabetes Mellitus	GLP-1 Agonists may be approved when all the following criteria are met: 1. Diagnosis of Type 2 diabetes; **AND** 2. The patient meets the appropriate age limit for the requested product: a) <u>For lixisenatide, semaglutide, tirzepatide:</u> 18 years of age or older; **OR** b) <u>For dulaglutide:</u> 10 years of age or older; **AND**

	3. Documentation of HbA1c ≥ 6.5 measured within the past 12 months; **AND** 4. History of failure, defined as inability to achieve glycemic control; intolerance; contraindication or clinically inappropriate to **ALL (a-c)** of the following used separately or simultaneously for a minimum of 90 days: a. Metformin at maximum or highest tolerated dose b. One preferred SGLT2 inhibitor c. One preferred GLP-1 If all the above criteria are met, the request will be approved for **12 months.**
	Criteria (Reauthorization)
	1. Documentation showing HbA1c has improved from baseline If all the above criteria are met, the request will be approved for **12 months.**
Patients with Type 2 diabetes and established cardiovascular disease or multiple cardiovascular risk factors who are at risk for major adverse cardiovascular events	GLP-1 Agonists may be approved when all the following criteria are met: 1. Diagnosis of Type 2 diabetes; **AND** 2. Patient has established atherosclerotic cardiovascular disease (ASCVD) or risk factors (see Appendix below); **AND** 3. Documentation of HbA1c ≥ 6.5 measured within the past 12 months; **AND** 4. History of failure, defined as inability to achieve glycemic control; intolerance; contraindication or clinically inappropriate to **ALL (a and b)** of the following used separately or simultaneously for a minimum of 90 days: a. One preferred SGLT2 inhibitor; **AND** b. Liraglutide If all the above criteria are met, the request will be approved for **12 months.**
	Criteria (Reauthorization)
	1. Documentation showing positive clinical response If all the above criteria are met, the request will be approved for **12 months.**

Appendix

ASCVD Defined As:	Cardiovascular Risk Factors include (but not limited to):
• Coronary heart disease - Myocardial infarction - Angina	• Dyslipidemia • Hypertension • Current tobacco use

- Coronary artery disease • Cerebrovascular disease - Transient ischemic attack - Ischemic stroke • Peripheral artery disease • Aortic atherosclerotic disease	• Obesity/overweight • Family history of premature ASCVD • Chronic kidney disease • Metabolic syndrome • Presence of albuminuria

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
Dulaglutide (TRULICITY)	• 18 mg per 28 days
Exenatide (BYETTA)	• 560 mcg per 28 days
Exenatide Extended Release (BYDUREON BCISE)	• 8 mg per 28 days
Liraglutide (VICTOZA)	• 50.4 mg per 28 days
Lixisenatide (ADLYXIN)	• Initial: 140 mcg x 14 days • Maintenance: 560 mcg x 28 days
Semaglutide subcutaneous (OZEMPIC)	• 8 mg per 28 days
Semaglutide tablet (RYBELSUS)	• 3 mg tablet: #30 tablets per 30 days • 7 mg tablet: #30 tablets per 30 days • 14 mg tablet: #30 tablets per 30 days
Tirzepatide (MOUNJARO)	• 60 mg per 28 days

References

1. Adlyxin (lixisenatide) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; January 2019.
2. Bydureon (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2020.
3. Glucagon-like peptide 1 receptor agonists for the treatment of type 2 diabetes mellitus. UpToDate. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed July 19, 2021. https://www.uptodate.com/contents/glucagon-like-peptide-1-receptor-agonists-for-the-treatment-of-type-2-diabetes-mellitus?source=history_widget
4. Ozempic (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; April 2021.
5. Rybelsus (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; January 2020.
6. Standards of Medical Care In Diabetes. Diabetes Care. https://care.diabetesjournals.org/content/diacare/suppl/2020/12/09/44.Supplement_1.DC1/DC_44_S1_final_copyright_stamped.pdf. Published January 2021. Accessed October 27, 2021.
7. Trulicity (dulaglutide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; November 2022.

History

Date	Action and Summary of Changes
06/14/2021	New policy created
08/18/2021	Approved by DUR Board
09/02/2021	Added established cardiovascular disease or risk of cardiovascular disease in patients with Type 2 diabetes indication

10/12/2022	Version 1 Update: Added Mounjaro and updated dose and quantity limits.
09/29/2023	Version 1 Update: 1. Updated quantity limit for Ozempic 2. Updated medical necessity language
11/27/2023	Removed 2b from clinical criteria section.
02/07/2024	Version 1 Update: 1. Updated age indication for dulaglutide 2. Updated quantity limits for Byetta, Victoza, and Adlyxin