Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist and Glucose-Dependent Insulinotropic Polypeptide (GIP)/ Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist

Override(s)	Approval Duration
Prior Authorization	1 year

Glucogon-Like-Peptide-1 (GLP-1) Receptor Agonists

Medications	Quantity Limit	Comments
Ozempic (semaglutide)	0.25 mg/dose, 0.5 mg/dose (2 mg prefilled pen): 1 prefilled pen per 28 days 1 mg/dose (4 mg prefilled pen): 1 prefilled pen (1 carton) per 28 days 2 mg/dose (8 mg prefilled pen): 1 prefilled pen (1 carton) per 28 days	Preferred
Rybelsus (semaglutide)	3 mg tablet: 1 carton (30 tablets) per one time fill 7 mg, 14 mg tablets: 1 carton (30 tablets) per 30 days	
Trulicity (dulaglutide)	4 prefilled pens/syringes per 28 days	
Victoza (liraglutide)	1 box per 30 days	

Adlyxin (lixisenatide)	Starter Pack: 1 pack (2 pens) per one time fill (28 day supply) Maintenance Pack: 1 pack (2 pens) per 28 days	Non-Preferred
Bydureon (exenatide extended release) Bydureon BCise (exenatide extended release)	4 vials/prefilled pens per 28 days 4 auto-injector pens per 28 days	
Byetta (exenatide)	1 prefilled pen per 30 days	

Glucose-Dependent Insulinotropic Polypeptide (GIP)/Glucogon-Like-Peptide-1 (GLP-1) Receptor Agonists

Medications	Quantity Limit	Comments
Mounjaro (tirzepatide)	4 pens per 28 days	Preferred

APPROVAL CRITERIA

Requests for a preferred GLP-1 receptor agonist or GIP/GLP-1 receptor agonist may be approved when the following criteria are met:

I. Individual meets one of the following:
   A. Requesting Mounjaro and 18 years of age or older; **OR**
   B. Requesting Trulicity or Victoza and 10 years of age or older; **OR**
   C. Requesting Ozempic or Rybelsus and 18 years of age or older;

AND

II. Individual has a diagnosis of type 2 diabetes;

AND

III. Documentation is provided that diagnosis has been verified by history of:
   A. Hemoglobin A1c (A1C) greater than or equal to 6.5%; **OR**
   B. Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL (after fasting for at least 8 hours); **OR**
   C. 2 hour plasma glucose greater than or equal to 200 mg/dL as part of an oral glucose tolerance test (75 g oral glucose after fasting for at least 8 hours); **OR**

D. Symptoms of hyperglycemia (including polyuria, polydipsia, polyphagia) and a random plasma glucose greater than or equal to 200 mg/dL;

AND

IV. Individual has had a trial and inadequate response or intolerance to metformin (AACE 2023). Medication samples/coupons/discount cards are excluded from consideration as a trial.;
OR

V. Individual has a contraindication to metformin therapy;
OR

VI. If requesting Ozempic, Trulicity or Victoza, individual has a history of atherosclerotic cardiovascular disease (ASCVD) including one or more of the following:
   A. Acute coronary syndrome;
   B. Coronary artery disease (CAD);
   C. History of myocardial infarction (MI);
   D. Stable or unstable angina;
   E. Coronary or other arterial revascularization;
   F. Stroke;
   G. Transient ischemic attack (TIA);
   H. Peripheral arterial disease (PAD).

Requests for a non-preferred GLP-1 receptor agonist may be approved when the following criteria are met:

I. Individual meets one of the following:
   A. Requesting Bydureon/BCise and 10 years of age or older; **OR**
   B. Requesting Adlyxin or Byetta and 18 years of age or older;

AND

II. Individual has a diagnosis of type 2 diabetes;

AND

III. Documentation is provided that diagnosis has been verified by history of:
   A. Hemoglobin A1c (A1C) greater than or equal to 6.5%; **OR**
   B. Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL (after fasting for at least 8 hours); **OR**
   C. 2 hour plasma glucose greater than or equal to 200 mg/dL as part of an oral glucose tolerance test (75 g oral glucose after fasting for at least 8 hours); **OR**
   D. Symptoms of hyperglycemia (including polyuria, polydipsia, polyphagia) and a random plasma glucose greater than or equal to 200 mg/dL;

AND

IV. One of the following:
    A. Individual has had a trial and inadequate response or intolerance to metformin (AACE 2023). Medication samples/coupons/discount cards are excluded from consideration as a trial.;
    OR
    B. Individual has a contraindication to metformin therapy;

AND

V. Documentation is provided that individual has had a trial and inadequate response or intolerance to two preferred agents. Medication samples/coupons/discount cards are excluded from consideration as a trial.

A GLP-1 receptor agonist or GIP/GLP-1 receptor agonist may not be approved for any of the following:

I. Individual with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) or a personal or family history of medullary thyroid carcinoma (MTC); **OR**
II. Individual is requesting for treatment of type 1 diabetes; **OR**
III. Individual is requesting for the treatment of prediabetes; **OR**
IV. Individual is requesting for the treatment of obesity; **OR**
V. Individual is requesting for weight loss; **OR**
VI. Individual is requesting Bydureon/BCise (exenatide extended-release) with an eGFR less than 45 mL/min/1.73 m^2; **OR**
VII. Individual is requesting Byetta (exenatide) with an eGFR less than 30 mL/min/1.73 m^2; **OR**
VIII. Individual is using in combination with another GLP-1 receptor agonist (including but not limited to Saxenda, Wegovy, Soliqua or Xultophy); **OR**
IX. Individual is using in combination with a DPP4 inhibitor (including but not limited to Janumet/XR, Januvia, Jentadueto/XR, Kazano, Kombiglyze XR, Nesina, Onglyza, Oseni, Tradjenta, Glyxambi, Qtern, Steglujan or Trijardy XR).

Note:
Most of the GLP-1 receptor agonists and GIP/GLP-1 receptor agonists have a black box warning for risk of thyroid C-cell tumors. GLP-1 receptor agonists have been found to cause thyroid C-cell tumors at clinically relevant exposure in rats. It is unknown whether GLP-1 receptor agonists cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans. Most GLP-1 receptor agonists are contraindicated in individuals with a personal or family history of MTC or in individuals with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Individuals using GLP-1 receptor agonists should be educated on the potential risk of MTC and symptoms of thyroid tumors.

Key References:

1. American Diabetes Association. Standard of Care in Diabetes – 2023. Available at: https://diabetesjournals.org/care/issue/46/Supplement_1 Accessed on March 9, 2023.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: May 10, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
5. Samson SL, Vellanki P, Blonde L, et. al. American Association of Clinical Endocrinologists (AACE) Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm – 2023 Update. *Endocrine Practice*. 2023;29:305-340.
6. US Food and Drug Administration. FDA Drug Safety Communication: FDA revises warnings regarding use of the diabetes medicine metformin in certain patients with reduced kidney function. Last updated: November 14, 2017. Available at https://www.fda.gov/Drugs/DrugSafety/ucm493244.htm. Accessed: May 9, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.