Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist Step Therapy

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit	Comments
Ozempic (semaglutide)	0.25mg/dose, 0.5mg/dose: 1 prefilled pen per 28 days 1mg/dose (2 mg prefilled pen: 2 prefilled pens (1 carton) per 28 days 1 mg/dose (4 mg prefilled pen): 1 prefilled pens (1 carton) per 28 days 2 mg/dose (8 mg prefilled pen): 1 prefilled pen (1 carton) per 28 days	Preferred
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 autoinjector pens per 28 days	
Byetta (exenatide)	1 prefilled pen per 30 days	
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	

APPROVAL CRITERIA

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

I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of metformin; **OR**;

II. Individual has a contraindication to metformin therapy.

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

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

AND

I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred GLP-1 receptor agonist;
II. May approve Rybelsus if the individual and/or caretaker is unable to administer and injectable GLP-1 receptor agonist.

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

I. Individual is requesting Bydureon/BCise (exenatide extended-release) with an eGFR less than 45 mL/min/1.73 m^2; **OR**
II. Individual is requesting Byetta (exenatide) with an eGFR less than 30 mL/min/1.73 m^2; **OR**
III. Individual is requesting for the treatment of prediabetes (A1C <6.5%); **OR**
IV. Individual is requesting for the treatment of obesity.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 16, 2021.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Garber AJ, Handelsman Y, Grunberger G, et. al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) on the Comprehensive Type 2 Diabetes Management Algorithm – 2020 Executive Summary. *Endocrine Practice*. 2020;26:107-139.

4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. 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: January 14, 2021.

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.