Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	NA

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)	0.25 mg/dose, 0.5 mg/dose: 1 prefilled pen per 28 days 1 mg/dose: 2 prefilled pens (1 carton) per 28 days	Preferred
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	
Tanzeum (albiglutide)	4 prefilled pens per 28 days	
Trulicity (dulaglutide)	4 prefilled pens/syringes per 28 days	

APPROVAL CRITERIA

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	NA

Requests for Ozempic or Victoza 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) and inadequate response or intolerance to metformin; **OR**
II. Individual has a contraindication to metformin therapy.

Requests for a non-preferred GLP-1 receptor agonist (Adlyxin, Bydureon, Bydureon BCise, Byetta, Rybelsus, Tanzeum or Trulicity) 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

II. 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 (Ozempic or Victoza);

OR

III. May approve Rybelsus if the individual and/or caretaker is unable to administer an 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 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: September 28, 2019.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Garber AJ, Abrahamson MJ, Barzilay JI, et. al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm – 2019 Executive Summary. *Endocrine Practice*. 2019;25:69-100.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	NA

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 15, 2019.

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.

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