Pharmacy Policy Bulletin: J-1300 Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs) for Diabetes – Commercial and Healthcare Reform	
Number: J-1300	**Category:** Managed Rx Coverage
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial (1., 2., or 3.)**: **1.** Rx Mgmt Performance = Deterrent/Patent Extenders **2.** Rx Mgmt Performance = Deterrent/Patent Extenders + Guideline **3.** Rx Mgmt Performance = MRXC = Yes **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1300-002	**Original Date:** 08/02/2023
Effective Date: 09/25/2023	**Review Date:** 08/02/2023

Drugs Product(s):	• Bydureon BCise (exenatide extended-release) • Byetta (exenatide) • Mounjaro (tirzepatide) • Ozempic (semaglutide) • Rybelsus (semaglutide) • Trulicity (dulaglutide) • Victoza (liraglutide)

FDA-Approved Indication(s):	• Bydureon BCise
	  o Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with T2DM
	• Byetta
	  o Adjunct to diet and exercise to improve glycemic control in adults with T2DM
	• Mounjaro
	  o Adjunct to diet and exercise to improve glycemic control in adults with T2DM
	• Ozempic
	  o Adjunct to diet and exercise to improve glycemic control in adults with T2DM
	  o Reduce the risk of major adverse cardiovascular events in adults with T2DM and established cardiovascular disease
	• Rybelsus
	  o Adjunct to diet and exercise to improve glycemic control in adults with T2DM
	• Trulicity
	  o Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with T2DM

	○ Reduce the risk of major adverse cardiovascular events in adults with T2DM who have established cardiovascular disease or multiple cardiovascular risk factors • Victoza ○ Adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus ○ Reduce the risk of major adverse cardiovascular events in adults with T2DM and established cardiovascular disease

Background:	• This policy is to be used in conjunction with other utilization management policies for the requested medication, if applicable, based on the member's benefit. • Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) activate GLP-1 receptors to augment glucose-dependent insulin secretion and slow gastric emptying leading to increased satiety. GLP-1 RAs lower fasting plasma glucose and reduce postprandial glucose excursions. • Type 2 diabetes mellitus (T2DM) is an impairment in the way the body regulates and uses glucose resulting in high levels of glucose circulating in the bloodstream. Hyperglycemia can lead to disorders of the circulatory, nervous, and immune systems. • According to the American Diabetes Association (ADA) Standards of Medical Care in Diabetes guideline, first-line therapy for the treatment of T2DM should be based on a patient's comorbidities, patient-centered treatment factors, cost and access considerations, and management needs. For most patients, the first-line therapy will be metformin and comprehensive lifestyle modifications. Other medications, such as GLP-1 RAs and sodium-glucose cotransporter 2 (SGLT2) inhibitors, may be considered as first-line therapy for individuals with type 2 diabetes mellitus and patient-specific factors, such as high risk or established atherosclerotic cardiovascular disease (ASCVD), chronic kidney disease, and/or heart failure. Subsequent therapies in the regimen should be tailored to comorbidities, patient-centered treatment factors, and management needs. • Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity, and Victoza are not indicated for obesity; Saxenda (liraglutide) and Wegovy (semaglutide) are the only GLP-1 RAs FDA-approved for the treatment of obesity. • Prescribing Considerations: ○ GLP-1 RAs should not be used in combination with dipeptidyl peptidase IV (DPP-IV) inhibitors. ○ GLP-1 RAs should not be used in a patient receiving concomitant Saxenda (liraglutide) or Wegovy (semaglutide).

Approval Criteria

I. Approval Criteria
When a benefit, coverage of a GLP-1 RA may be approved when the following criterion is met **(A.)**:
A. The member has a diagnosis of type 2 diabetes mellitus (ICD-10: E11).

II. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of GLP-1 RAs in this policy will not be approved for a sole diagnosis of obesity.
II. Members requesting a non-preferred GLP-1 RA (i.e., Bydureon BCise, Byetta) must also meet criteria outlined in policy J-0661, if applicable, based on the member's benefit.

III. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

IV. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

Members who meet the criterion as outlined below **(A.)** will receive automatic authorization at the pharmacy point of service without documentation of additional information. Claims will automatically adjudicate on-line, with no prior authorization required.

A. There is a claim for one (1) anti-diabetes medication (e.g., metformin, acarbose, bromocriptine, colesevelam, miglitol, amylin analogs, insulin, sulfonylureas, thiazolidinediones, dipeptidyl peptidase IV [DPP IV] inhibitors, sodium-glucose cotransporter 2 [SGLT2] inhibitors), **excluding GLP-1 RAs**, in the member's prescription drug claims history within the previous 720 days.

References:

1. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2023
2. American Diabetes Association. Standards of Care in Diabetes-2023. *Diabetes Care*. 2023;46(Suppl 1): S1-S291.