Pharmacy Medical Necessity Guidelines: Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists

Effective: April 1, 2023

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0988	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Adlyxin (lixisentide) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. It is administered once daily within one hour before the first meal of the day.

Byetta (exenatide) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It is injected subcutaneously within 60 minutes prior to morning and evening meals (or before the two main meals of the day, approximately six hours or more apart).

Bydureon (exenatide) is an extended-release formulation of exenatide and should not be co-administered with Byetta. Bydureon is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus. Bydureon 2 mg is administered by subcutaneous injection once every seven days, at any time of day, with or without meals.

Mounjaro (tirzepatide) is a glucose-dependent insulinotropic polypeptide (GIP) receptor and GLP-1 receptor agonist that is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Mounjaro is a subcutaneous injection that is dosed once weekly at any time of day with regard to meals.

Ozempic (semaglutide) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Ozempic is also indicated to reduce the major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease. Ozempic is administered once weekly at any time of day, with or without meals.

Rybelsus (semaglutide) is the first oral GLP1 agonist approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. It should be administered at least 30 minutes before the first food, beverage, or other oral medications of the day with no more than 4 ounces of plain water only. Waiting less than 30 minutes, or take with food, beverages (other than plain water), or other oral medications will lessen the effect of Rybelsus. Waiting more than 30 minutes to eat may increase the absorption of Rybelsus.

Victoza (liraglutide) is indicated as an adjunct to diet and exercise to improve glycemic control in patients 10 years of age and older with type 2 diabetes mellitus. Victoza is also indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease. Victoza is injected subcutaneously once daily at any time of day, regardless of meals.

Trulicity (dulaglutide) is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus. Trulicity is also indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors. Trulicity is administered subcutaneously once weekly at any time of day.

COVERAGE GUIDELINES

The plan may authorize coverage of a GLP-1 agonist for Members when **all** of the following criteria are met:

1. Member has had an inadequate response, intolerance, or contraindication to metformin at the highest tolerated dose

AND

2. The Member has a diagnosis of type 2 diabetes

AND

3. The Member meets ONE of the following:
   a. There is a clinical rationale why the Member cannot take (e.g., clinical inappropriateness of therapy with or an inadequate response, intolerance, or contraindication to) at least one additional generic oral antidiabetic agent besides metformin. Examples include sulfonylureas (glimepiride, glipizide, glyburide), thiazolidinedione (pioglitazone), meglitinide analogues (nateglinide, replaglinide), and DPP-4 inhibitor (alogliptin).

   OR

   b. The Member has established cardiovascular disease (CVD) (e.g., ASCVD[†], heart failure) and the request is for Ozempic, Trulicity, or Victoza

   OR

   c. The Member has two or more cardiovascular risk factors* and the request is for Trulicity

AND

3. **Rybelsus only:** Member has had an inadequate response, intolerance, or contraindication to an injectable GLP-1 agonist or the provider submits documentation that the member cannot administer an injectable GLP-1 agonist

[†]ASCVD defined as:
- Coronary heart disease (CHD) (myocardial infarction, angina, coronary artery disease)
- Cerebrovascular disease (e.g., transient ischemic attack, ischemic stroke)
- Peripheral artery disease
- Aortic atherosclerotic disease

*Cardiovascular risk factors include (but not limited to):
- Dyslipidemia
- Hypertension
- Current tobacco use
- Obesity/overweight
- Family history of premature ASCVD
- Chronic kidney disease
- Metabolic syndrome
- Presence of albuminuria

LIMITATIONS

1. Documentation of a Member having needle phobia does not qualify as a medically acceptable contraindication or clinical inappropriateness for an injectable GLP-1 agonist.
2. Rybelsus will be limited to 30 tablets per 30 days.
3. Mounjaro will be limited to 4 pens per 28 days.

CODES

None

REFERENCES

1. Adlyxin (lixisenatide) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; June 2022.
2. American Diabetes Association. Standards of medical care in diabetes – 2022. *Diabetes Care*. 2022;45(Suppl. 1):S1-S264.
3. Bydureon (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca; July 2022.
4. Byetta (exentaide) [prescribing information]. Wilmington, DE: AstraZeneca; June 2022.
5. Mounjaro (tirzepatide) [prescribing information]. Indianapolis, IN: Lilly US, LLC; September 2022.
6. Ozempic (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk; October 2022.
7. Rybelsus (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk; June 2022.
8. Trulicity (dulaglutide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; December 2022.
9. Victoza (liraglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk; June 2022.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.
Subsequent endorsements date(s) and changes made:

1. January 10, 2023: Effective April 1, 2023, updated criteria to require diagnosis of type 2 diabetes. Removed Tanzeum from the MNG due to product discontinuation.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services