Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Incretin Mimetics Step Therapy

Effective: October 1, 2024

Guideline Type	☐ Prior Authorization ☐ Non-Formulary ☒ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

The following are the preferred incretin mimetics for type 2 diabetes covered by the plan:

Bydureon BCise (exenatide extended-release) injectable is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus.

Byetta (exenatide) injection is a GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Mounjaro (tirzepatide) injection is a glucose-dependent insulinotropic polypeptide (GIP) receptor and GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Ozempic (semaglutide) injection is a GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. It has been indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

Rybelsus (semaglutide) tablet is a GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Trulicity (dulaglutide) injection is a GLP-1 receptor agonist 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. It has been indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.

Victoza (liraglutide) injection is a GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus. It has been indicated to reduce the risk of major cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

Clinical Guideline Coverage Criteria

Note: Prescriptions that meet the initial step therapy requirements will adjudicate **automatically** at the point of service. If the patient does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan for patients who do not meet the step therapy criteria at the point of service.

Please refer to the table below for medications subject to this policy:

Drug	
Step-1	
Preferred oral hypoglycemic agents (such as metformin, sulfonylurea, thiazolidinedione, DPP-IV inhibitor, SGLT2 inhibitor, or combination of these agents)	Covered as listed on formulary
Step-2	
Bydureon BCise	Requires prior use of a drug on Step-1
Byetta	
Mounjaro	
Ozempic	
Rybelsus	
Trulicity	
Step-3	
Victoza	Requires prior use of **TWO** drugs on Step-2

Automated Step Therapy Coverage Criteria
The following stepped approach applies to coverage of the Step-2 and Step-3 medications by the plan:

Step 1: Medications on Step-1 are covered as listed on the formulary without prior authorization.

Step 2: The plan may cover Step-2 medications if the following criteria are met:
a. The patient has had a 30-day trial of one (1) Step-1 medication or the requested Step-2 medication within the previous 365 days as evidenced by a paid claim under the prescription benefit administered by the plan.

Step 3: The plan may cover Step-3 medications if the following criteria are met:
a. The patient has had a trial of **two (2)** Step-2 medications or the requested Step-3 medication within the previous 365 days as evidenced by a paid claim under the prescription benefit administered by the plan.

Coverage Criteria for Patients not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale
Step 2: The plan may cover medications on **Step-2** if the following criteria are met per physician attestation:

1. Documented diagnosis of type 2 diabetes, as defined by one of the following labs, as documented in the medical record:
   - A1C ≥ 6.5%
   - Fasting plasma glucose (FPG) ≥ 126mg/dL
   - 2-hour plasma glucose (2-h PG) ≥ 200 mg/dL during oral glucose tolerance test (OGTT)
   - Random plasma glucose (PG) ≥ 200 mg/dL

Step 3: The plan may cover medications on **Step-3** if the following criteria are met per physician attestation:

1. Documented diagnosis of type 2 diabetes, as defined by one of the following labs, as documented in the medical record:
   - A1C ≥ 6.5%
   - Fasting plasma glucose (FPG) ≥ 126mg/dL
   - 2-hour plasma glucose (2-h PG) ≥ 200 mg/dL during oral glucose tolerance test (OGTT)
   - Random plasma glucose (PG) ≥ 200 mg/dL

   AND
2. The patient has a physician documented trial and failure with a 30-day trial of at least two (2), or contraindication or intolerance to all of the Step-2 medications

Limitations

1. The plan will not cover the preceding incretin mimetics if it is solely being used for weight loss. Please refer to the Pharmacy Medical Necessity Guideline for Weight Loss Medications.
2. Step therapy point of service coding does not apply to any non-formulary medications. For a non-formulary medication

request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Bydureon BCise (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2023.
2. Byetta (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2022.
3. Victoza (liraglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; July 2023.
4. Trulicity (dulaglutide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; December 2022.
5. Ozempic (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; September 2023.
6. Rybelsus (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; January 2024.
7. Mounjaro (tirzepatide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; July 2023.

Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- March 14, 2023: Added Mounjaro to Incretin Mimetics Step Therapy Medical Necessity Guideline (effective March 20, 2023).
- March 12, 2024: No changes.
- April 9, 2024: Effective May 1, 2024:
  - Updated the automated look-back history on the trial of one (1) Step-1 or the requested Step-2 medication within the previous 180 days to 365 days as evidenced by a paid claim under the prescription benefit administered by the plan
  - Administrative update to clarify the length of 30-day trial of one (1) Step-1 medication in the automated step therapy criteria
  - Administrative update to clarify that when automated step is not met, the following criteria are met per physician attestation: documented diagnosis of type 2 diabetes, as defined by one of the following labs, as documented in the medical record: A1C ≥ 6.5%, FPG ≥ 126mg/dL, 2 hr PG ≥ 200 mg/dL during OGTT, or random PG ≥ 200 mg/dL
  - Removed criterion when automated step is not met for trial and failure, or is currently taking one oral hypoglycemic agent (such as metformin, sulfonylurea, thiazolidinedione, DPP-IV inhibitor, SGLT2 inhibitor, or combination of these agents
  - Administrative update to overview that Trulicity is indicated in patients aged 10 years and older with type 2 diabetes
  - July 2024 e-vote: Effective October 1, 2024, updated step therapy coverage criteria for Victoza as a Step-3 medication.

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.