Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Incretin Mimetics

Effective: January 1, 2026

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[SM] – 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. It has also been indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney 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. It is 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 are at high risk for these events.

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.

Clinical Guideline Coverage Criteria

I. Clinical Guideline Coverage Criteria for Formularies Subject to Step Therapy

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	Premium, Value, Select, Core MA, Direct, and ConnectorCare Formularies
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	

Automated Step Therapy Coverage Criteria

The following stepped approach applies to coverage of the Step-2 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:

- 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.

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

II. Clinical Guideline Coverage Criteria for Formularies Subject to Prior Authorization (Core ME, Core NH, Core RI formularies)

The plan may authorize coverage of Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, or Trulicity 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. Trial and failure of 30-day trial or is currently taking ONE oral hypoglycemic agent (such as metformin, sulfonylurea, thiazolidinedione, DPP-IV inhibitor, SGLT2 inhibitor, or combination of these agents

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 2025.
2. Byetta (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2025.
3. Victoza (liraglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; May 2025.
4. Trulicity (dulaglutide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; June 2025.
5. Ozempic (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; October 2025.
6. Rybelsus (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; October 2025.
7. Mounjaro (tirzepatide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; September 2025.

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 9, 2024: Effective October 1, 2024, updated step therapy coverage criteria for Victoza as a Step-3 medication.
- October 8, 2024: Effective January 1, 2025, removed ‘Step Therapy’ from title of MNG. Removed Victoza from the step therapy program. Administrative update to distinguish clinical guideline coverage for formularies subject to step therapy. Added clinical guideline coverage criteria for formularies subject to prior authorization to require documented diagnosis of type 2 diabetes and trial/failure of 30-day trial or is currently taking one oral hypoglycemic agent.
- March 11, 2025: Administrative update to indicate Premium, Value, Core MA, Direct, and ConnectorCare as formularies subject to step therapy, and Core ME, Core NH, and Core RI as formularies subject to prior authorization. Administrative update to overview with Ozempic’s expanded indication in adults with type 2 diabetes mellitus and chronic kidney disease.
- November 4, 2025: Effective January 1, 2026, administrative update to add Select as formulary subject to step therapy. Administrative update to overview that Rybelsus is indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus who are at high risk for these events.

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.