Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Generic Metformin-Extended Release

Effective: July 14, 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

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

Fortamet (metformin extended-release) and **Glumetza (metformin extended-release)** are indicated for the management of type 2 diabetes mellitus (noninsulin dependent) when hyperglycemia cannot be managed with diet and exercise alone.

According to the American Diabetes Association, if not contraindicated and if tolerated, metformin is a preferred initial pharmacological agent for type 2 diabetes. The agent has a long-standing evidence base for efficacy and safety and may reduce risk of cardiovascular events and death.

Metformin should also be considered for the prevention of type 2 diabetes in patients with prediabetes, especially with a body mass index >35 kg/m^2, age less than 60 years, and women with prior gestational diabetes mellitus.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of metformin extended-release (ER) (Fortamet and Glumetza), when **ALL** the following criteria are met:

1) For **generic Fortamet** (metformin 500 and 1,000 mg ER tablets):
   a. Documentation from the provider that treatment with generic Glucophage XR (metformin ER) is clinically inappropriate

   AND

   b. For daily doses of 1,000 mg, in addition to the above criterion, documentation of clinical inappropriateness of treatment with two 500 mg generic Glucophage XR (metformin ER) tablets is required for approval.

2) For **generic Glumetza** (metformin 500 and 1,000 mg ER tablets):
   a. Documentation from the provider that treatment with generic Glucophage XR (metformin ER) **AND** generic Fortamet (metformin ER) is clinically inappropriate

   AND

   b. For daily doses of 1,000 mg, in addition to the above criteria, documentation of clinical inappropriateness of treatment with two 500 mg generic Glucophage XR (metformin ER) tablets is required for approval.

Limitations

1. 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. American Diabetes Association. Standards of Medical Care in Diabetes - 2026. Diabetes Care. 2025 Jan;49(Suppl 1).
2. Metformin drug information. UpToDate [database on the Internet]. Wolters Kluwer. Accessed 2024 May 29.

Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 11, 2023: No changes
- July 9, 2024: No changes
- July 8, 2025: No changes.
- July 14, 2026: Administrative update to remove CareLink from the Medical Necessity Guideline template.

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.