Pharmacy Medical Necessity Guidelines:
Generic Metformin Extended-Release

Effective: April 14, 2026

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: 617.673.0939	

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Metformin is indicated for the management of type 2 diabetes mellitus (noninsulin dependent) when hyperglycemia cannot be managed with diet and exercise alone.

COVERAGE GUIDELINES

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

Note: 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

Note: 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

None

CODES

None

REFERENCES

1. American Diabetes Association. Standards of medical care in diabetes – 2024. *Diabetes Care*. 2024;47(Suppl. 1):S1-S321.
2. Fortamet (metformin extended-release tablet) [prescribing information]. Fort Lauderdale, FL: Actavis Laboratories FL, Inc; November 2018.
3. Glucophage/Glucophage XR (metformin/metformin extended-release tablet) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; May 2018.
4. Glumetza (metformin extended-release tablet) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals; February 2024.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 11, 2023: No changes.
2. April 9, 2024: Effective May 1, 2024, updated RxUM fax number.
3. April 8, 2025: No changes
4. April 14, 2026: No changes.

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