Pharmacy Medical Necessity Guidelines: Generic Metformin Extended-Release

Effective: January 1, 2021

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:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988
MM: 888.415.9055
PRECERT: 617.972.9409

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.

According to the American Diabetes Association, if not contraindicated and if tolerated, metformin is the 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.

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 - 2016. Diabetes Care. 2016 Jan;39(Suppl 1):S1-112.
2. Metformin drug information. UpToDate [database on the Internet]. Wolters Kluwer. Accessed 2020 May 28.

APPROVAL HISTORY

September 13, 2016: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
- September 12, 2017: No changes
- October 16, 2018: Administrative update to template
- April 9, 2019: No changes
- June 9, 2020: No changes
- November 24, 2020: Effective 1/1/2021, removed Tufts Health Together from the MNG.

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.