TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Ranolazine Extended-Release Tablet

Effective: March 16, 2020

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[SM] – 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

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

OVERVIEW

FDA-APPROVED INDICATIONS

Ranexa (ranolazine extended-release) is indicated for the treatment of chronic angina. Ranexa may be used with beta-blockers, nitrates, calcium channel blockers, anti-platelet therapy, lipid-lowering therapy, ACE inhibitors, and angiotensin receptor blockers.

COVERAGE GUIDELINES

The plan may authorize coverage of ranolazine for Members when the following criteria are met and limitations do not apply:

1. The Member is diagnosed with angina

AND

2. The Member tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with the following:
   a) long-acting nitrate **AND**
   b) beta-blocker or a calcium channel blocker

LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria

CODES

None

REFERENCES

1. Ranexa [prescribing information]. Foster City, CA: Gilead Sciences Inc; October 2019.
2. Fihn SD, Gardin JM, Abrams J. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association task force on practice guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Intervention and Thoracic Surgeons. *Circulation;*2012;126(25):e354-e471.
3. Managed Care Dossier. Gilead Information Services. June 2009.
4. Morrow DA, Scirica BM, Karwatowska-Prokopczuk E, et al. Effects of ranolazine on recurrent cardiovascular events in patients with non-ST-elevation acute coronary syndromes: the MERLIN-TIMI 36 randomized trial. JAMA. 2007;297(16):1775-1783.

APPROVAL HISTORY

June 14, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 12, 2015: Reviewed by the Pharmacy and Therapeutics Committee; approval duration modified to 2 years; renewal criteria added.
2. September 16, 2015: Approval duration approved for life of plan.
3. January 1, 2016: Administrative change to rebranded template.
4. September 13, 2016: No changes.
5. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
6. September 12, 2017: Administrative update, removed language regarding approval length as requests will be approved for life of plan
7. October 22, 2018: Administrative update to template.
8. April 9, 2019: Administrative update, added "Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria" to the limitations section of the MNG.
9. March 10, 2020: Effective March 16, 2020, administrative update, updated the title of the MNG from "Ranexa" to "Ranolazine Extended-Release Tablets."

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.