Pharmacy Medical Necessity Guidelines: Fenofibrate Medications

Effective: June 15, 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℠ – 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

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Fenofibrate products are indicated to:

- Reduce low-density lipoprotein cholesterol, total cholesterol, triglycerides, and apolipoprotein B, and to increase high-density lipoprotein cholesterol (HDL-C) in adults with primary hypercholesterolemia or mixed dyslipidemia (Fredrickson types IIa and IIb).
- Adjunctive therapy to diet for treatment of adult patients with severe hypertriglyceridemia (Fredrickson types IV and V hyperlipidemia).

Trilipix is also indicated as an adjunct to diet in combination with a statin to reduce triglycerides and increase HDL-C in patients with mixed dyslipidemia and coronary heart disease (CHD) or a CHD risk equivalent who are on optimal statin therapy.

Generic fenofibrate in the following strengths and formulations are covered without prior authorization: 48 mg, 54 mg, 145 mg, and 160 mg tablets, and 67 mg, 134 mg, and 200 mg capsules.

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred fenofibrate medication for Members when the following criterion is met:

1. Documentation the Member has tried and failed therapy with at least two preferred fenofibrate product on the Preferred Drug List of comparable strength, or of higher strength if the request is based on ineffectiveness of a lower strength product

LIMITATIONS

1. Coverage for all non-preferred fenofibrate medications will be limited to once daily dosing.
2. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Non-covered Medications criteria.

CODES

None

REFERENCES

1. Tricor [package insert]. North Chicago, IL: AbbVie; November 2018.
2. Antara [package insert]. Baltimore, MD: Lupin Pharmaceuticals; April 2019.
3. Lofibra [package insert]. Horsham, PA: Teva; July 2017.
4. Fibricor [package insert]. Athens, GA: Athena Bioscience; September 2019.
5. Triglide [package insert]. East Brunswick, NJ: Casper Pharma; April 2019.
6. Lipofen [package insert]. Montgomery, AL: Kowa Pharmaceuticals America Inc; May 2019.

7. Trilipix [package insert]. North Chicago, IL: AbbVie; November 2018.
8. Fenoglide [package insert]. Bridgewater, NJ: Salix Pharmaceuticals; May 2018.
9. Berglund L, Brunzell JD, Goldberg AC, et al. Evaluation and treatment of hypertriglyceridemia: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2012;97(9):2969-2989
10. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2014;129:S1.
11. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guidelines on the management of blood cholesterol: A report on the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2018;25708;DOI: 10.1016/j.jacc2018.11.003.

APPROVAL HISTORY

January 17, 2008: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. July 8, 2014: No changes
2. September 12, 2014: No changes
3. July 14, 2015: Approval duration modified to 2 years, limitations section updated.
4. September 15, 2015: Approval duration modified to life of plan.
5. January 1, 2016: Administrative change to rebranded template.
6. July 12, 2016: Removed limitation #2 "Quantities that exceed the quantity limit will be reviewed according to the Drugs w/ Quantity Limitations criteria."
7. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
8. August 8, 2017: No changes.
9. August 7, 2018: Updated the criteria to require Members try and fail at least two preferred fenofibrate products prior to approval of a nonpreferred agent.
10. June 11, 2019: Administrative changes made to template.
11. June 9, 2020: Effective 6/15/2020, updated MNG to reflect that fenofibrate 48 mg and 145 mg tablets are preferred products.

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.