Pharmacy Medical Necessity Guidelines: Fenofibrate Medications

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

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).

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 products 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. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Non-covered Medications criteria.

CODES

None

REFERENCES

1. Antara [package insert]. Baltimore, MD: Lupin Pharmaceuticals; March 2023.
2. 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.
3. Fenoglide [package insert]. Bridgewater, NJ: Salix Pharmaceuticals; June 2021.
4. Fibricor [package insert]. Athens, GA: Athena Bioscience; December 2020.
5. 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.
6. Lipofen [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc; September 2021.
7. 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.
8. Tricor [package insert]. North Chicago, IL: AbbVie; June 2021.
9. Triglide [package insert]. East Brunswick, NJ: Casper Pharma; June 2021.
10. Trilipix [package insert]. North Chicago, IL: AbbVie; June 2021.

APPROVAL HISTORY

October 11, 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