MEDICAL MUTUAL®

Drug Policy

Policy:	**Fenofibrate Step Therapy Policy**	**Annual Review Date:** **09/19/2024**
Impacted Drugs:	**Generic fenofibrate 40 mg & 120 mg, Triglide**	**Last Revised Date:** **09/19/2024**

OVERVIEW

Fenofibrate/fenofibric acid is a lipid regulating agent available in various oral formulations. The products are indicated as an adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (total-C), triglycerides (TG) and apolipoprotein B (Apo B), and to increase high-density lipoprotein cholesterol (HDL-C) in adults with **primary hypercholesterolemia or mixed dyslipidemia**. The products are also indicated for the treatment of adults with **hypertriglyceridemia**.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one Step 1 product within the 130-day look-back period is excluded from Step Therapy.

Step 1: Generic fenofibrate tablets (48 mg, 54 mg, 145 mg, and 160 mg), generic fenofibrate capsules (43 mg, 67 mg, 130 mg, 134 mg, and 200 mg), generic fenofibric acid capsules (45 mg and 135 mg)

Step 2: Triglide, fenofibrate 40 mg, 120 mg

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a Step 1 medication, then authorization for a Step 2 medication may be given.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 years
B) *Extended Approval:* 2 years

Step Therapy Exception Criteria

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Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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5. Fenoglide® tablets [prescribing information]. Bridgewater NJ: Salix Pharmaceuticals; May 2019.
6. Trilipix® capsules, delayed-release [prescribing information]. North Chicago, IL: AbbVie; November 2018.
7. Fibricor® tablets [prescribing information]. Athens, GA: Athena Bioscience; September 2019.
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9. Fenofibrate tablets [prescribing information]. Sunrise, FL: Cipla; June 2017.
10. Fenofibric acid delayed-release pellets [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; December 2016.
11. Fenofibric acid delayed release capsules [prescribing information]. Baltimore, MD: Lupin; June 2015.
12. Fenofibrate capsules [prescribing information]. Montgomery, AL: H2-Pharma; May 2014.
13. ACCORD Study Group, Ginsberg NH, Elam MB, Lovato LC, et al. Effects of combination lipid therapy in type 2 diabetes mellitus. *N Engl J Med*. 2010;362(17):1563-1574.
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