Select Fenofibrate Products

Policy # 00720
Original Effective Date: 01/01/2021
Current Effective Date: 11/11/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider generic fenofibrate 120 mg tablets, generic fenofibrate 40 mg tablets, generic fenofibrate 130 mg capsules, brand Fenofibrate 50 mg capsules, brand Fenofibrate 150 mg capsules, brand Fenofibrate 90 mg capsules, generic fenofibric acid 35 mg tablets, generic fenofibric acid 135 mg capsules, brand Fenoglide®‡ 40 mg tablets, brand Fenoglide 120 mg tablets, brand Lipofen®‡ 50 mg capsules, brand Lipofen 150 mg capsules, brand Fibricor®‡ 35 mg tablets, brand Fibricor 105 mg tablets, brand Trilipix®‡ 45 mg capsules, and brand Trilipix 135 mg capsules to be **eligible for coverage**** when the following patient selection criterion is met.

Patient Selection Criteria

Coverage eligibility for generic fenofibrate 120 mg tablets, generic fenofibrate 40 mg tablets, generic fenofibrate 130 mg capsules, brand Fenofibrate 50 mg capsules, brand Fenofibrate 150 mg capsules, brand Fenofibrate 90 mg capsules, generic fenofibric acid 35 mg tablets, generic fenofibric acid 135 mg capsules, brand Fenoglide 40 mg tablets, brand Fenoglide 120 mg tablets, brand Lipofen 50 mg capsules, brand Lipofen 150 mg capsules, brand Fibricor 35 mg tablets, brand Fibricor 105 mg tablets, brand Trilipix 45 mg capsules, and brand Trilipix 135 mg capsules will be considered when the following criterion is met:

- Patient has tried and failed (e.g., intolerance or inadequate response) TWO of the following fenofibrate formulations: GENERIC 134 mg, 200 mg, or 67 mg capsules or GENERIC 145 mg, 160 mg, 48 mg, or 54 mg tablets, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.

Select Fenofibrate Products

Policy # 00720
Original Effective Date: 01/01/2021
Current Effective Date: 11/11/2024

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of generic fenofibrate 120 mg tablets, generic fenofibrate 40 mg tablets, generic fenofibrate 130 mg capsules, brand Fenofibrate 50 mg capsules, brand Fenofibrate 150 mg capsules, brand Fenofibrate 90 mg capsules, generic fenofibric acid 35 mg tablets, generic fenofibric acid 135 mg capsules, brand Fenoglide 40 mg tablets, brand Fenoglide 120 mg tablets, brand Lipofen 50 mg capsules, brand Lipofen 150 mg capsules, brand Fibricor 35 mg tablets, brand Fibricor 105 mg tablets, brand Trilipix 45 mg capsules, and brand Trilipix 135 mg capsules when the patient selection criterion is not met to be **not medically necessary.****

Background/Overview

Fenofibrate products are available in both brand and generic formulations and are used primarily for the reduction of high cholesterol and high triglycerides. Certain strengths of generic and brand fenofibrate/fenofibric acid products provide an economic disadvantage due to their pricing, while providing no additional clinical value. The products mentioned in this policy have been targeted for this reason. There are many more affordable options on the market in the fenofibrate class that are equally efficacious in treating high cholesterol and high triglyceride levels.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

These products are approved as an adjunctive therapy to diet to reduce elevated low-density lipoprotein cholesterol, total cholesterol, triglycerides and apolipoprotein B, and to increase high-density lipoprotein cholesterol in adult patients with primary hypercholesterolemia or mixed dyslipidemia. They are also approved as an adjunctive therapy to diet for treatment of adult patients with severe hypertriglyceridemia.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Select Fenofibrate Products

Policy # 00720
Original Effective Date: 01/01/2021
Current Effective Date: 11/11/2024

The intent of this policy is to target the generic fenofibrate 120 mg tablets, generic fenofibrate 40 mg tablets, generic fenofibrate 130 mg capsules, brand Fenofibrate 50 mg capsules, brand Fenofibrate 150 mg capsules, brand Fenofibrate 90 mg capsules, generic fenofibric acid 35 mg tablets, generic fenofibric acid 135 mg capsules, brand Fenoglide 40 mg tablets, brand Fenoglide 120 mg tablets, brand Lipofen 50 mg capsules, brand Lipofen 150 mg capsules, brand Fibricor 35 mg tablets, brand Fibricor 105 mg tablets, brand Trilipix 45 mg capsules, and brand Trilipix 135 mg capsules, which are priced at an economic disadvantage to other alternatives such as generic fenofibrate 134 mg, 200 mg, or 67 mg capsules and generic fenofibrate 145 mg, 160 mg, 48 mg, or 54 mg tablets, while offering no clinical advantage.

References

1. Fenofibrate tablets 120 mg [package insert]. Various manufacturers. Updated May 2019.
2. Fenofibrate tablets (40 mg, 145 mg, 160 mg, 48 mg, 54 mg) [package insert]. Various manufacturers. Various Update Dates.
3. Fenofibrate capsules (130 mg, 134 mg, 200 mg, or 67 mg) [package insert]. Various manufacturers. Various Update Dates.
4. Trilipix capsules [package insert]. Abbvie, Inc. North Chicago, Illinois. Updated June 2021
5. Lipofen capsules [package insert]. Kowa Pharmaceuticals. Montgomery, Alabama. Updated June 2021.
6. Fenoglide tablets [package insert]. Salix Pharmaceuticals. Bridgewater, New Jersey. Updated June 2021.
7. Fenofibrate 50 mg and 150 mg capsules [package insert]. Ani Pharmaceuticals. Baudette, Minnesota. Updated June 2021.
8. Fenofibric acid 35 mg tablet [package insert]. Various manufacturers. Various Update Dates.
9. Fenofibric acid 135 mg capsule [package insert]. Various manufacturers. Various Update Dates.
10. Fibricor tablets [package insert]. Aralex Pharmaceuticals, Inc. Princeton, New Jersey. Updated May 2018.
11. Fenofibrate 30 mg and 90 mg capsules [package insert]. Lupin Pharmaceuticals, Inc. Baltimore, Maryland. Updated October 2021.

Select Fenofibrate Products

Policy # 00720
Original Effective Date: 01/01/2021
Current Effective Date: 11/11/2024

Policy History

Original Effective Date: 01/01/2021
Current Effective Date: 11/11/2024

10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. New policy.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. Added the following products to the policy: generic fenofibrate 40 mg tablets, generic fenofibrate 130 mg capsules, brand Fenofibrate 50 mg capsules, brand Fenofibrate 150 mg capsules, generic fenofibric acid 35 mg tablets, generic fenofibric acid 135 mg capsules, brand Fenoglide 40 mg tablets, brand Fenoglide 120 mg tablets, brand Antara 30 mg capsules, brand Antara 90 mg capsules, brand Lipofen 50 mg capsules, brand Lipofen 150 mg capsules, brand Tricor 48 mg tablets, brand Tricor 145 mg tablets, brand Fibricor 35 mg tablets, brand Fibricor 105 mg tablets, brand Trilipix 45 mg capsules, and brand Trilipix 135 mg capsules.
10/07/2021	Medical Policy Committee review
10/13/2021	Medical Policy Implementation Committee approval. Removed Tricor from the list of newly added products.
10/06/2022	Medical Policy Committee review
10/11/2022	Medical Policy Implementation Committee approval. Added brand Fenofibrate 30 mg capsules and brand Fenofibrate 90 mg capsules to the policy.
10/05/2023	Medical Policy Committee review
10/11/2023	Medical Policy Implementation Committee approval. Removed brand Fenofibrate 30 mg capsules from the policy due to the product being discontinued.
10/03/2024	Medical Policy Committee review
10/08/2024	Medical Policy Implementation Committee approval. Removed brand Antara from policy due to the product being discontinued.

Next Scheduled Review Date: 10/2025

Select Fenofibrate Products

Policy # 00720
Original Effective Date: 01/01/2021
Current Effective Date: 11/11/2024

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.