Select Fenofibrate Products

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

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 oral tablets to be **eligible for coverage**** when the following patient selection criterion is met.

Patient Selection Criteria

Coverage eligibility for generic fenofibrate 120 mg oral tablets 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 oral capsules or GENERIC 145 mg, 160 mg, 48 mg, or 54 mg oral 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.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of generic fenofibrate 120 mg oral tablets 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. Unfortunately, certain strengths of generic fenofibrate products provide an economic disadvantage due to their pricing, while providing no additional clinical value. One particular strength is the 120 mg oral tablets. Luckily, there are many

more affordable options on the market in the fenofibrate class that offer an equally efficacious option.

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

The intent of this policy is to target the generic fenofibrate 120 mg oral tablets, which are priced at an economic disadvantage to other alternatives such as generic fenofibrate 134 mg, 200 mg, or 67 mg oral capsules and generic fenofibrate 145 mg, 160 mg, 48 mg, or 54 mg oral tablets, while offering no clinical advantage.

References

1. Fenofibrate tablets 120 mg [package insert]. Various manufacturers. Updated May 2019.
2. Fenofibrate tablets (145 mg, 160 mg, 48 mg, 54 mg) [package insert]. Various manufacturers. Various Update Dates.
3. Fenofibrate capsules (134 mg, 200 mg, or 67 mg) [package insert]. Various manufacturers. Various Update Dates.

Policy History

Original Effective Date: 01/01/2021
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10/01/2020 Medical Policy Committee review
10/07/2020 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 10/2021

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**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.