

Clinical Pharmacy Program Guidelines for Fenofibrate

Program	Step Therapy
Medication	Fenofibrate tablet 54mg, 160mg Fenofibrate micronized capsule 67mg, 134mg, 200mg
Markets in Scope	Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2009
Pharmacy and Therapeutics Approval Date	4/2020
Effective Date	6/2020

1. Background:

Hypercholesterolemia

Fenofibrate tablet 54mg, 160mg and fenofibrate micronized capsule 67mg, 134mg and 200mg are indicated as adjunctive therapy to diet to reduce elevated low-density lipoprotein cholesterol (LDL-C), total cholesterol (Total-C), triglycerides, and apolipoprotein B (Apo B), and to increase high-density lipoprotein cholesterol (HDL-C) in adult patients with primary hypercholesterolemia or mixed dyslipidemia.

Hypertriglyceridemia

Fenofibrate tablet 54mg, 160mg and fenofibrate micronized capsule 67mg, 134mg and 200mg are indicated as adjunctive therapy to diet for treatment of adult patients with severe hypertriglyceridemia.

2. Coverage Criteria:

<p>A. <u>Authorization Criteria</u></p> <p>1. Fenofibrate tablet 54mg, 160mg or fenofibrate micronized capsule 67mg, 134mg, 200mg will be approved when one of the following circumstances is met:</p> <p style="margin-left: 40px;">a. The medication is being prescribed for use in combination with a statin (e.g. simvastatin, pravastatin, lovastatin)</p> <p style="text-align: center;">-OR-</p>

b. The patient did not exhibit an adequate response to treatment with gemfibrozil for at least 90 days.

-OR-

c. The patient experienced an intolerance/adverse reaction to previous therapy with gemfibrozil or has a documented contraindication to treatment with gemfibrozil.

Authorization will be issued for 12 months.

3. Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. fenofibrate tablets [package insert] Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2019
2. fenofibrate capsule, micronized [package insert] Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2019.

Program	Step Therapy - fenofibrate
Change Control	
Date	Change
3/2009	New policy
9/2012	Revision
11/2016	Annual review, updated policy template and added standard authorization duration of 12 months
11/2017	Annual review. Updated references.
11/2018	Annual review. Updated references. Minor language updates with no change to clinical intent.
12/2019	Annual review. Updated background. Updated references.
4/2020	Revised header and background to clarify which fenofibrate formulations are preferred.