UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Fenofibrate

Program	Step Therapy
Medication	Lofibra capsules (fenofibrate micronized), Lofibra tablets (fenofibrate)
Issue Date	3/2009
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

1. Background:

Hypercholesterolemia
Lofibra is indicated as adjunctive therapy to diet to reduce elevated LDL-C, Total-C, triglycerides, and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia (Fredrickson Types IIa and IIb). Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol when response to diet and non-pharmacological interventions alone has been inadequate.

Hypertriglyceridemia
Lofibra is indicated as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia (Fredrickson Types IV and V hyperlipidemia). Improving glycemic control in diabetic patients showing fasting chylomicronemia will usually reduce fasting triglycerides and eliminate chylomicronemia thereby obviating the need for pharmacologic intervention.

2. Coverage Criteria:

A. Automated Step Therapy Criteria

1. A claim for **fenofibrate tablets or capsules** will process at the point of sale if the patient's drug fill history shows a fill of a statin (e.g. simvastatin, pravastatin, lovastatin) **OR** a 90 day trial of gemfibrozil.

B. Requests that DO NOT Meet Automated Step Criteria

1. **Fenofibrate tablets or capsules** will be approved for patients who have not met the automated step criteria when **one** of the following circumstances is met:

   a. Fenofibrate is being prescribed for use in combination with a statin (e.g. simvastatin, pravastatin, lovastatin)

-OR-

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-

d. The patient has a documented contraindication to treatment with gemfibrozil.

Authorization will be issued for 12 months.

3. References:

1. Lofibra Tablets® Prescribing Information. Gate Pharmaceuticals, January 2010.
2. Lofibra Capsules® Prescribing Information. Gate Pharmaceuticals, January 2010.
3. Clinical Pharmacology Gold Standard. 2017.
.
4. Cheng AY and Leiter LA. Implications of recent clinical trials for the National CholesterolEducation Program Adult Treatment Panel III guidelines..*Curr Opin Cardiol*. 2006; 21:400-404.
5. Pejic RN, Lee, DT. Hypertriglyceridemia. J Am Board Fam Med. 2006;19(3):310-316.
6. Oh RC and Lanier JB. Management of Hypertriglyceridemia. *Am Fam Physician*. 2007;75: 1365-1372.
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 adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2014; 129 (suppl 2): S1-S45.
8. Berglund L, Brunzel JD, Goldberg AC, et al. Evaluation and Treatment of Hypertriglyceridemia: An Endocrine Society Clnical Practice Guideline. *J Clin Endocrinol Metab*. Sep 2012: 97(9): 2969-2989.

Program	Step Therapy - Lofibra capsules (fenofibrate micronized), Lofibra tablets (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.