

Commercial Step Criteria

Effective: April 2010

Step Therapy Name: Brand Fenofibrates

Step 1 Agent(s): Trilipix DR oral capsules, Tricor oral tablets, fenofibrate 67mg/134mg/200mg oral capsules, fenofibrate 54mg/160mg oral tablet

Step 2 Agent(s): Antara, Fenoglide oral tablets, Fenofibrate 160mg (brand) oral tablet, Fibricor oral tablets, Lofibra, Triglide oral tablet

Medication/Class Description: Fenofibrate is indicated as an adjunctive therapy to diet for the reduction of 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 (Fredrickson types IIa and IIb).

Fenofibrate is also indicated as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia (Fredrickson types IV and V hyperlipidemia).

Required Medical Information:

1. Diagnosis
2. Previous therapies tried and failed
3. Medical history

Exclusion Criteria:

1. Patients with severe renal dysfunction, including those receiving dialysis
2. Patients with active liver disease, including those with primary biliary cirrhosis and unexplained persistent liver function abnormalities
3. Patients with pre-existing gallbladder disease
4. Patients with a known hypersensitivity to fenofibrate
5. Patients that are nursing (breast-feeding)

Age Restrictions: 18 years of age and older

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Exceptions for Stepped Medications:

- A. Patient has a diagnosis of Primary Hypercholesterolemia and Mixed Dyslipidemia OR Severe Hypertriglyceridemia; AND
- B. Patient has had a trial and failure, intolerance, or contraindication of a Step 1 Agents, defined as
 - a. Failure to decrease lipid levels; OR
- C. Patient has an intolerance or contraindication to a Step 1 Agents, defined as (but not limited to):
 - a. Allergic reaction; OR
 - b. Adverse drug reactions.

References:

1. Fibracor full prescribing information. AR Scientific, Philadelphia, PA,
2. Lofibra full prescribing information, Gate Pharmaceuticals, Sellersville, PA
3. Triglide full prescribing information, Shionogi Pharmaceuticals, Atlanta, GA
4. Fenoglide full prescribing information, Shore Therapeutics, Stamford, CT

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	4/2010
2	Update	Moved to updated policy Previous CCI Revision: 6/12, 2/13, 9/15, 2/17, 1/19	All	2/28/2020
3	Update	Specified targets: Antara, Lofibra	Step 2 Agents	7/31/2020