

STEP THERAPY POLICY

- POLICY:** Fenofibrate Step Therapy Policy
- Antara[®] (fenofibrate capsules – Lupin)
 - Fenofibrate (fenofibrate capsule – H2 Pharma)
 - fenofibrate capsules and tablets (generic – multiple manufacturers)
 - fenofibric acid tablets and capsules (generic – multiple manufacturers)
 - Fenoglide[®] (fenofibrate tablets – Salix/Bausch, generic)
 - Fibracor[®] (fenofibric acid tablets – Athena Bioscience, generic)
 - Lipofen[®] (fenofibrate capsules – Kowa)
 - TriCor[®] (fenofibrate tablets – AbbVie, generic)
 - Triglide[®] (fenofibrate tablets – Casper)
 - Trilipix[®] (fenofibric capsules, delayed-release – AbbVie, generic)

REVIEW DATE: 11/08/2023

OVERVIEW

Fenofibrate/fenofibric acid is a lipid regulating agent available in various oral formulations.¹⁻¹² The products are indicated as an adjunct to diet:

- To reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (total-C), triglycerides (TG) and apolipoprotein B (Apo B), and to increase high-density lipoprotein cholesterol (HDL-C) in adults with **primary hypercholesterolemia or mixed dyslipidemia**.
- For the treatment of adults with **hypertriglyceridemia**.

A limitation of use is that the products have not been shown to reduce coronary heart disease morbidity and mortality in patients with type 2 diabetes mellitus.¹⁻¹² The products have been studied for use in combination with other agents.^{13,14} Also, many fenofibrate products are available, both brand and generic, and some have undergone reformulations.¹⁵

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: generic fenofibrate capsules (43 mg, 67 mg, 130 mg, 134 mg, and 200 mg), generic fenofibrate tablets (48 mg, 54 mg, 145 mg, and 160 mg), generic fenofibric acid capsules (45 mg and 135 mg), generic fenofibric acid tablets (35 mg and 105 mg)

Step 2: Antara, Fenofibrate, fenofibrate 40 mg, fenofibrate 50 mg, fenofibrate 120 mg, fenofibrate 150 mg, Fenoglide, Fibracor, Lipofen, Tricor, Triglide, Trilipix

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

REFERENCES

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2. Antara® capsules [prescribing information]. Baltimore, MD: Lupin; June 2021.
3. Triglide® tablets [prescribing information]. East Brunswick, NJ: Casper; June 2021.
4. Lipofen® capsules [prescribing information]. Montgomery, AL: Kowa; June 2021.
5. Fenoglide® tablets [prescribing information]. Bridgewater, NJ: Salix/Bausch; June 2021.
6. Trilipix® capsules, delayed-release [prescribing information]. North Chicago, IL: AbbVie; March 2021.
7. Fibricor® tablets [prescribing information]. Athens, GA: Athena Bioscience; June 2021.
8. Fenofibrate capsules [prescribing information]. Baudette, MN: ANI/Cipher; June 2021.
9. Fenofibrate tablets [prescribing information]. Warren, NJ: Cipla; July 2021.
10. Fenofibric acid delayed-release pellets [prescribing information]. Morgantown, WV: Mylan; June 2021.
11. Fenofibric acid delayed release capsules [prescribing information]. Wilmington, DE: Graviti; September 2019.
12. Fenofibrate capsules [prescribing information]. Montgomery, AL: H2-Pharma; May 2014.
13. ACCORD Study Group, Ginsberg NH, Elam MB, Lovato LC, et al. Effects of combination lipid therapy in type 2 diabetes mellitus. *N Engl J Med.* 2010;362(17):1563-1574.
14. McKeage K, Keating GM. Fenofibrate. A review of its use in dyslipidemia. *Drugs.* 2011;71(14):1917-1946.
15. Downing NS, Ross JS, Jackevicius CA, Krumholz HM. Avoidance of generic competition by Abbott Laboratories' fenofibrate franchise. *Arch Intern Med.* 2012;172(9):724-730.