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)
- Fibricor® (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

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

Fenofibrate product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

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, Fibricor, Lipofen, Tricor, Triglide, Trilipix

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

REFERENCES

1. TriCor® tablets [prescribing information]. North Chicago, IL: AbbVie; June 2021.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/26/2022
Annual Revision	No criteria changes.	11/08/2023