Effective Date 1/15/2024
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Coverage Policy Number IP0339

Fenofibrates

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Related Coverage Resources

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.

Overview

This policy supports medical necessity review for the following fenofibrate products:

- Antara® (fenofibrate)
- fenofibrate 30 mg and 90 mg capsules
- Fenoglide® (fenofibrate)

Additional criteria that support the review for medical necessity exceptions of non-covered products are located in the Non-Covered Product Table by the respective plan type and drug list where applicable.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Antara (fenofibrate 30 mg and 90 mg capsules)	Documentation of failure, contraindication, or intolerance to **THREE** of the following: 1. fenofibric acid DR capsule (Trilipix® generic) 2. fenofibrate tablet (Tricor®/Lofibra® generic) 3. fenofibric acid tablet (Fibricor® generic) 4. fenofibrate capsule (Lipofen™ generic)
fenofibrate 30 mg and 90 mg capsules	Documentation of failure, contraindication, or intolerance to **THREE** of the following: 1. fenofibric acid DR capsule (Trilipix generic) 2. fenofibrate tablet (Tricor/Lofibra generic) 3. fenofibric acid tablet (Fibricor generic) 4. fenofibrate capsule (Lipofen generic)
Fenoglide (fenofibrate 40 mg and 120 mg tablets)	Documentation of failure, contraindication, or intolerance to **THREE** of the following: 1. fenofibric acid DR capsule (Trilipix generic) 2. fenofibrate tablet (Tricor/Lofibra generic) 3. fenofibric acid tablet (Fibricor generic) 4. fenofibrate capsule (Lipofen generic)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of fenofibrate products is considered medically necessary for continued use when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months.

Reauthorization approval duration: up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

Background

OVERVIEW
Fenofibrate/fenofibric acid are lipid-regulating agents 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]

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; December 2016.
11. Fenofibric acid delayed release capsules [prescribing information]. Wilmington, DE: Graviti; September 2019.
12. Fenofibrate [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.