



## Uniform Formulary Medical Necessity Criteria for Antilipidemics II

**Drug Class** - Antilipidemics II. This class includes three types of medications that affect cholesterol levels: the fibric acid derivatives (gemfibrozil and fenofibrate), the bile acid sequestrants (cholestyramine, colestevlam, and colestipol), and prescription omega-3 fatty acids (Lovaza, formerly Omacor).

**Background** - After evaluating the relative clinical and cost effectiveness of the antilipidemic II agents, the DoD P&T Committee recommended that the following medications be designated as non-formulary. This recommendation has been approved by the Director, TMA.

- Antara (micronized fenofibrate)
- Lovaza, formerly Omacor (prescription omega-3 fatty acids)
- Tricor (nanocrystallized fenofibrate)
- Trilipix (fenofibric acid)
- Welchol (colesevelam)

**Effective Date:** 21 November 2007; 28 October 2009

Patients currently using a nonformulary agent may wish to ask their doctor to consider a formulary alternative.

### Uniform Formulary Status, Copays, and Therapeutic Alternatives for Antilipidemic II Agents <sup>1-6</sup>

Uniform Formulary Status	Medication	MTF (Up to a 90-day supply)	TMOP (Up to a 90-day supply)	Retail (Up to a 30-day supply)
Non-Formulary (Tier 3)	Antara (micronized fenofibrate) <sup>5</sup> Lovaza, formerly Omacor (prescription omega-3 fatty acids) Tricor (nanocrystallized fenofibrate) <sup>5</sup> Welchol (colesevelam) Trilipix (fenofibric acid) <sup>5</sup>	Not available <sup>2</sup>	\$22	\$22
Formulary (Tier 2)	Triglide (IDD-P fenofibrate) <sup>5</sup>	\$0	\$9	\$9
Generic (Tier 1)	Cholestyramine / aspartame Cholestyramine / sucrose Colestipol Micronized fenofibrate (other than Antara) <sup>5</sup> Non-micronized fenofibrate <sup>5</sup> Fenoglide(melt-dose fenofibrate) <sup>6</sup>	\$0	\$3	\$3

IDD-P = insoluble drug delivery microparticle

1. Active duty copay always \$0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary.
2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) the prescription must be written by an MTF provider, MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred AND 2) medical necessity is established.
3. [Mandatory generic policy](#) applies to both formulary and non-formulary medications.
4. Other antilipidemics not included in the Antilipidemic II class include HMG CoA-reductase inhibitors (statins), ezetimibe (Zetia), simvastatin/ezetimibe (Vytorin), niacin, and niacin/statin combinations. Statins, ezetimibe, and bile acid sequestrants primarily lower LDL cholesterol, while the fibric acid derivatives, Lovaza (formerly Omacor, prescription omega-3 fatty acids), and niacin primarily lower triglycerides and raise HDL cholesterol. Various combinations of antilipidemics may be used depending on the patient's needs.
5. Fenofibrate products with a reduced particle size (i.e., melt-dose, micronized/IDD-P and nanocrystallized fenofibrate) are designed to address bioavailability issues.
6. **Special Note about Fenoglide Cost Share:** Although Fenoglide is a branded product, the DoD P&T Committee recommended that it be made available at a generic cost share based on its clinical and cost effectiveness compared to gemfibrozil, Lovaza (formerly Omacor), and other fenofibrate formulations.

### Medical Necessity Criteria

#### **Antara (micronized fenofibrate), Tricor (nanocrystallized fenofibrate) and Trilipix (fenofibric acid)**

The \$22 non-formulary copay for Antara, Tricor or Trilipix may be reduced to the \$9 formulary copay if the patient meets the following criterion.

1. The use of Fenoglide (melt-dose fenofibrate) is contraindicated (e.g., due to hypersensitivity to a dye or other inert ingredient).

#### **Lovaza (formerly Omacor)**

The \$22 non-formulary copay for Lovaza (formerly Omacor) may be reduced to the \$9 formulary copay if the patient meets any of the following criteria.

1. The use of BOTH of the following formulary alternatives is contraindicated: fibric acid derivatives (e.g., gemfibrozil, fenofibrate) and niacin.
2. The patient has experienced or is likely to experience significant adverse effects from BOTH of the following formulary alternatives: fibric acid derivatives (e.g., gemfibrozil, fenofibrate) and niacin. (An example might be a patient who cannot take fibric acid derivatives due to a history of myopathy and who cannot tolerate niacin).
3. BOTH of the following formulary alternatives have resulted in therapeutic failure: fibric acid derivatives (e.g., gemfibrozil, fenofibrate) and niacin.

## Welchol (colesevelam)

The \$22 non-formulary copay for Welchol may be reduced to the \$9 formulary copay if the patient meets any of the following criteria.

1. The use of BOTH of the following formulary alternatives is contraindicated: cholestyramine and colestipol.
2. The patient has experienced or is likely to experience significant adverse effects from BOTH of the following formulary alternatives: cholestyramine and colestipol.
3. BOTH of the following formulary alternatives have resulted in therapeutic failure: cholestyramine and colestipol.
4. The patient has a history of GI obstruction and requires treatment with a bile acid sequestrant.
5. The patient is pregnant and requires treatment with a bile acid sequestrant.

Medical necessity criteria for Antara, Lovaza (formerly Omacor), Tricor, and Welchol recommended by the DoD Pharmacy & Therapeutics Committee at the May 2007 meeting and approved by the Director, TMA on 24 July 2007. For more information, please see the May 2007 [DoD P&T Committee minutes](#). Addition of Fenoglide to the LIP2 class by the DoD Pharmacy & Therapeutics Committee at the June 2008 meeting and approved by the Director, TMA on 27 Aug 2008. Addition of Trilipix to the LIP2 class by the DoD Pharmacy & Therapeutics Committee at the May 2009 meeting and approved by the Director, TMA on 17 Aug 2009.

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