SmartPA Criteria Proposal

Drug/Drug Class:	Triglyceride Lowering Agents PDL Edit
First Implementation Date:	December 6, 2006
Proposed Date:	September 15, 2022
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☒ Existing Criteria ☐ Revision of Existing Criteria ☐ New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: The fibric acid derivatives (fibrates) are designed to lower triglycerides and to raise high-density lipoprotein (HDL). Fibrates have been shown to lower triglycerides by as much as 35-50% and to raise HDL by as much as 15-25%. Omega-3-Fatty Acids are present in fatty fish such as mackerel, lake trout, herring sardines, albacore tuna, and salmon and also in dietary supplements of fish oil concentrates, but large quantities of these products are required to reach therapeutic doses. Lovaza® is a highly purified ethyl ester concentrate of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), two kinds of omega-3-fatty acids. The major effect of Lovaza is to lower triglycerides, although the mechanism of action is not entirely understood. These agents should be used in addition to a diet restricted in saturated fat and cholesterol when the individual response has been inadequate.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Fenofibrate 54, 67, 134, 160, 200 mg (gen Lofibra®) • Fenofibrate 48, 145 mg (gen Tricor®) • Gemfibrozil	• Antara® • Fenofibrate (gen Antara®) • Fenofibrate (gen Fenoglide®) • Fenofibrate (gen Lipofen®) • Fenofibrate (gen Triglide®) • Fenofibric Acid (gen Fibricor®) • Fenofibric Acid (gen Trilipix®) • Fenoglide® • Fibricor® • Icosapent ethyl • Lipofen® • Lopid® • Lovaza® • Omega-3 Acid Ethyl Esters • Tricor® • Triglide® • Trilipix® • Vascepa®

Type of Criteria:	☐ **Increased risk of ADE**	☒ **Preferred Drug List**
	☐ **Appropriate Indications**	☐ **Clinical Edit**
Data Sources:	☒ **Only Administrative Databases**	☐ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Triglyceride Lowering Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents **OR**
  - For Lovaza or Vascepa therapy: Triglyceride levels ≥ 500 mg/dL allow first line therapy access

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:	X	Progress Notes:	
MedWatch Form:		Other:	

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: "Triglyceride Lowering Agents", UMKC-DIC; July 2022.
- Evidence-Based Medicine and Fiscal Analysis: "Triglyceride Lowering Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; July 2021.
- Grundy S, Stone N, Bailey A, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guidelines on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2018 June, 73(24) e285-e350.
- Virani SS, Morris PB, et. al. 2021 ACC Expert Consensus Decision Pathway on the Management of ASCVD Risk Reduction in Patients with Persistent Hypertriglyceridemia. J Am Coll Cardiol. 2021 June, 78(9). 960-993.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.