SmartPA Criteria Proposal

Drug/Drug Class:	Statins (HMG-CoA Reductase Inhibitors) and Combinations PDL Edit
First Implementation Date:	June 16, 2004
Revised Date:	January 12, 2023
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 statin drugs have already surpassed all other classes of medication in reducing the incidence of the major adverse outcomes of death, heart attack, and stroke. In the management of atherosclerotic vascular disease, lipid-lowering therapy with statins reduces the risk of cardiovascular events. The intensity of statin therapy is divided into three categories: high-intensity (lower LDL-C levels by ≥ 50%), moderate-intensity (lower LDL-C levels by 30-49%), and low-intensity (lower LDL-C levels by < 30%). Multiple drug interactions exist with the statin class and side effects may lead to dose or product adjustments, or discontinuation of therapy. Commonly reported side effects include myalgias, abdominal pain, nausea, and headache.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Atorvastatin • Ezetimibe • Lovastatin • Pravastatin • Rosuvastatin • Simvastatin	• Altoprev® • Amlodipine/Atorvastatin • Caduet® • Crestor® • Ezallor Sprinkle™ • Ezetimibe/Simvastatin • Fluvastatin • Fluvastatin ER • Lescol XL® • Lipitor® • Livalo® • Nexletol® • Nexlizet® • Pravachol® • Vytorin® • Zetia® • Zocor®

	• Zypitamag®

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: Statins (HMG-CoA Reductase Inhibitors) and Combinations
- 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

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
ALTOPREV 20 MG TABLET	LOVASTATIN ER	1 tablet per day
ALTOPREV 40 MG TABLET	LOVASTATIN ER	1 tablet per day
ALTOPREV 60 MG TABLET	LOVASTATIN ER	1 tablet per day
CRESTOR 5 MG TABLET	ROSUVASTATIN	1 tablet per day
CRESTOR 10 MG TABLET	ROSUVASTATIN	1 tablet per day
CRESTOR 20 MG TABLET	ROSUVASTATIN	1 tablet per day
CRESTOR 40 MG TABLET	ROSUVASTATIN	1 tablet per day
EZALLOR SPRINKLE 5 MG CAPSULE	ROSUVASTATIN	1 capsule per day
EZALLOR SPRINKLE 10 MG CAPSULE	ROSUVASTATIN	1 capsule per day
EZALLOR SPRINKLE 20 MG CAPSULE	ROSUVASTATIN	1 capsule per day
EZALLOR SPRINKLE 40 MG CAPSULE	ROSUVASTATIN	1 capsule per day
LIPITOR 10 MG TABLET	ATORVASTATIN	1 tablet per day
LIPITOR 20 MG TABLET	ATORVASTATIN	1 tablet per day
LIPITOR 40 MG TABLET	ATORVASTATIN	1 tablet per day
LIPITOR 80 MG TABLET	ATORVASTATIN	1 tablet per day
LIVALO 1 MG TABLET	PITAVASTATIN CALCIUM	1 tablet per day
LIVALO 2 MG TABLET	PITAVASTATIN CALCIUM	1 tablet per day
LIVALO 4 MG TABLET	PITAVASTATIN CALCIUM	1 tablet per day
NEXLETOL 180 MG TABLET	BEMPEDOIC ACID	1 tablet per day
NEXLIZET 180/10 MG TABLET	BEMPEDOIC ACID/EZETIMIBE	1 tablet per day
PRAVACHOL 80 MG TABLET	PRAVASTATIN	1 tablet per day
PRAVACHOL 10 MG TABLET	PRAVASTATIN	1 tablet per day
PRAVACHOL 20 MG TABLET	PRAVASTATIN	1 tablet per day
PRAVACHOL 40 MG TABLET	PRAVASTATIN	1 tablet per day
ZETIA 10 MG TABLET	EZETIMIBE	1 tablet per day

Required Documentation

Laboratory Results:	☐	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: “Lipotropics: Statins, Niacin Preparations, Cholesterol Absorption Inhibitors”, UMKC-DIC; July 2022.
- Evidence-Based Medicine and Fiscal Analysis: “Lipotropic Agents: Statins and Combination Products – 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.