SmartPA Criteria Proposal

Drug/Drug Class:	Statins (HMG-CoA Reductase Inhibitors) and Combinations PDL Edit
First Implementation Date:	June 16, 2004
Proposed Date:	September 17, 2020
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.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Atorvastatin • Lovastatin • Pravastatin • Rosuvastatin • Simvastatin	• Altoprev® • Amlodipine/Atorvastatin • Caduet® • Crestor® • Ezallor™ Sprinkle • Ezetimibe • Ezetimibe/Simvastatin • FloLipid • 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
LIPITOR 10 MG	ATORVASTATIN	1 tablet per day
LIPITOR 20 MG	ATORVASTATIN	1 tablet per day
LIPITOR 40 MG	ATORVASTATIN	1 tablet per day
LIPITOR 80 MG	ATORVASTATIN	1 tablet per day
ALTOPREV 20 MG	LOVASTATIN ER	1 tablet per day
ALTOPREV 40 MG	LOVASTATIN ER	1 tablet per day
ALTOPREV 60 MG	LOVASTATIN ER	1 tablet per day
PRAVACHOL 80 MG	PRAVASTATIN	1 tablet per day
PRAVACHOL 10 MG	PRAVASTATIN	1 tablet per day
PRAVACHOL 20 MG	PRAVASTATIN	1 tablet per day
PRAVACHOL 40 MG	PRAVASTATIN	1 tablet per day
CRESTOR 10 MG	ROSUVASTATIN	1 tablet per day
CRESTOR 20 MG	ROSUVASTATIN	1 tablet per day
CRESTOR 40 MG	ROSUVASTATIN	1 tablet per day
CRESTOR 5 MG	ROSUVASTATIN	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

1. Drug Effectiveness Review Project – “HMG-CoA Reductase Inhibitors (Statins) and Fixed-dose Combination Products Containing a Statin”. Center for Evidence-Based Policy, Oregon Health & Science University; November 2009/Updated April 2015; Evidence Scan April 2017.
2. Evidence-Based Medicine and Fiscal Analysis: “Lipotropic Agents: Statins and Combination Products – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; July 2020.
3. Evidence-Based Medicine Analysis: “Lipotropics: Statins, Niacin Preparations, Cholesterol Absorption Inhibitors, Combinations”, UMKC-DIC; June 2020.
4. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
5. USPDI, Micromedex; 2020.
6. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.