



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Statins (HMG-CoA Reductase Inhibitors) and Combinations PDL Edit
<b>First Implementation Date:</b>	June 16, 2004
<b>Revised Date:</b>	October 14, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> 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
	<ul style="list-style-type: none"> <li>Atorvastatin</li> <li>Lovastatin</li> <li>Pravastatin</li> <li>Rosuvastatin</li> <li>Simvastatin</li> </ul>	<ul style="list-style-type: none"> <li>Altoprev®</li> <li>Amlodipine/Atorvastatin</li> <li>Caduet®</li> <li>Crestor®</li> <li>Ezallor Sprinkle™</li> <li>Ezetimibe</li> <li><b>Ezetimibe/Rosuvastatin</b></li> <li>Ezetimibe/Simvastatin</li> <li>FloLipid</li> <li>Fluvastatin</li> <li>Fluvastatin ER</li> <li>Lescol XL®</li> <li>Lipitor®</li> <li>Livalo®</li> <li>Nexleto®</li> <li>Nexlizet®</li> <li>Pravachol®</li> <li>Vytorin®</li> <li>Zetia®</li> <li>Zocor®</li> <li>Zypitamag®</li> </ul>

Type of Criteria:  Increased risk of ADE  
 Appropriate Indications

Preferred Drug List  
 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:   
 MedWatch Form:

Progress Notes:   
 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.