

# SmartPA Criteria Proposal

|                                   |  |
|-----------------------------------|--|
| <b>Drug/Drug Class:</b>           | Statins (HMG-CoA Reductase Inhibitors) and Combinations<br>PDL Edit  |
| <b>First Implementation Date:</b> | June 16, 2004  |
| <b>Proposed Date:</b>             | September 17, 2020   |
| <b>Prepared For:</b>              | MO HealthNet   |
| <b>Prepared By:</b>               | MO HealthNet/Conduent  |
| <b>Criteria Status:</b>           | <input type="checkbox"/> Existing Criteria<br><input checked="" type="checkbox"/> Revision of Existing Criteria<br><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>Ezetimibe/Simvastatin</li> <li>FloLipid</li> <li>Fluvastatin</li> <li>Fluvastatin ER</li> <li>Lescol XL®</li> <li>Lipitor®</li> <li>Livalo®</li> <li>Nexletol™</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

### SmartPA PDL Proposal Form

© 2020 Conduent Business Services, LLC. All rights reserved. Conduent™ and Conduent Design™ are trademarks of Conduent Business Services, LLC in the United States and/or other countries.

Other company trademarks are also acknowledged.

## 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.