

SmartPA Criteria Proposal

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| Drug/Drug Class: | Statins (HMG-CoA Reductase Inhibitors) and Combinations PDL Edit |
| First Implementation Date: | June 16, 2004 |
| Proposed Date: | October 17, 2023 |
| Prepared For: | MO HealthNet |
| Prepared By: | MO HealthNet/Conduent |
| Criteria Status: | <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. The intensity of statin therapy is divided into three categories: high-intensity (lower LDL-C levels by $\geq 50\%$), 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 |
|-------------------------------|---|--|
| | <ul style="list-style-type: none"> Atorvastatin Ezetimibe Lovastatin Pravastatin Rosuvastatin Simvastatin | <ul style="list-style-type: none"> Altprev[®] Amlodipine/Atorvastatin Atorvaliq[®] Caduet[®] Crestor[®] Ezallor Sprinkle[™] Ezetimibe/Simvastatin Fluvastatin Fluvastatin ER Lescol XL[®] Lipitor[®] Livalo[®] Nexletol[®] Nexlizet[®] Pravachol[®] Vytorin[®] Zetia[®] Zocor[®] |

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- 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:
MedWatch Form:

Progress Notes:
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; April 2023.
- 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; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.