SmartPA Criteria Proposal

Drug/Drug Class:	Proprotein Convertase Subtilisin Kexin type 9 (PCSK9) Inhibitors PDL Edit
First Implementation Date:	January 10, 2019
Proposed Date:	September 15, 2022
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: Proprotein convertase subtilisin/kexin type 9 (PCSK9) is a hepatic protease which functions to regulate the amount of cholesterol in circulation. PCSK9 binds to and breaks down low-density lipoprotein receptors (LDLR), which are responsible for the removal of cholesterol. Praluent® and Repatha®, approved by the FDA in 2015, are monoclonal antibodies that bind to and inhibit PCSK9 from binding to LDLR resulting in a decrease in LDLR degradation. Leqvio®, FDA approved in 2021, is a siRNA, which utilizes RNA interference in hepatocytes to cause catalytic breakdown of mRNA for PCSK9 synthesis; therefore, increasing clearance of LDL. Praluent and Repatha are indicated for use as adjunct to diet, alone, or in combination with other lipid-lowering medications for the treatment of primary hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH), and to reduce the risk of myocardial infarction and stroke in patients with cardiovascular disease (CVD). Repatha is also indicated for risk reduction of coronary revascularization for adults with CVD while Praluent has the additional indication of risk reduction of unstable angina requiring hospitalization for adults with CVD. Leqvio is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or clinical atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Praluent® • Repatha®	• Leqvio®

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: Proprotein Convertase Subtilisin Kexin type 9 (PCSK9) Inhibitors
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented diagnosis of hypercholesterolemia or clinical atherosclerotic cardiovascular disease in the past year **AND**
- Documented compliance on high dose statin therapy (90/120 days) or documentation of intolerance to statin therapy **AND**
- Documentation of current lipid profile no less than 3 months old **AND**
- 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
- Documentation of cholesterol goals and current LDL levels required for renewal of authorization

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

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: “PCSK9”, UMKC-DIC; July 2022.
- Evidence-Based Medicine and Fiscal Analysis: “PCSK9 Inhibitors – 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.
- Leqvio [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. December 2021.

- Praluent [package insert]. Bridgewater, NJ: Sanofi-Aventis US LLC; April 2021.
- Repatha [package insert]. Thousand Oaks, CA: Amgen, September 2021.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.