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 16, 2021
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: Praluent® and Repatha®, approved by the FDA in 2015, are monoclonal antibodies that bind to and inhibit proprotein convertase subtilisin/kexin type 9 (PCSK9) from binding to low-density lipoprotein receptors (LDLR) resulting in a decrease in LDLR degradation. LDLR is the primary receptor responsible for clearing low-density lipoprotein cholesterol (LDL-C). PCSK9 inhibitors increase the number of LDLR receptors resulting in lower concentrations of LDL-C circulating in the body. 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. The 2018 Journal of the American College of Cardiology guidelines recommend PCSK9 inhibitors for high-risk patients who continue to have elevated LDL-C levels while taking high-intensity statins and ezetimibe.

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

Program-Specific Information:

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

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: 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 1 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

1. Evidence-Based Medicine and Fiscal Analysis: “PCSK9 Inhibitors – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; July 2021.
2. Evidence-Based Medicine Analysis: “PCSK9”, UMKC-DIC; June 2021.
3. Praluent (alirocumab) [prescribing information], Bridgewater, NJ: Sanofi-Aventis US LLC; April 2021.
4. Repatha (evolocumab) [prescribing information]. Thousand Oaks, CA: Amgen, February 2021.
5. 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 Cadiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2019 June, 73 (24) e285-e350. Accessed August 23, 2021.