SmartPA Criteria Proposal

Drug/Drug Class:	Proprotein Convertase Subtilisin Kexin type 9 (PCSK9) Binders PDL Edit
First Implementation Date:	January 10, 2019
Proposed Date:	September 17, 2020
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® are both proprotein convertase subtilisin kexin 9 (PCSK9) inhibitors, and effectively lower LDL cholesterol levels up to 67%, compared to statin reduction of up to 63%. At a minimum PCSK9s are equally effective in reducing LDL as high intensity statins, and for some individuals better at lowering LDL than high intensity statins. The PCSK9 LDL lowering can be additive to statin lowering. The FDA approved Praluent in July 2015, for use second line following maximally tolerated statin therapy, in patients with clinically diagnosed atherosclerotic heart disease and HeFH (heterozygous familial hypercholesterolemia), not HoFH (homozygous familial hypercholesterolemia). The FDA approved Repatha in August 2015 with similar indications, plus use in HoFH.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Repatha® (Amgen USA Mft)	• Praluent™ • Repatha® (Non-Amgen USA Mft)

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) Binders
- 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 2020.
2. Evidence-Based Medicine Analysis: “PCSK9”, UMKC-DIC; June 2020.
3. IPD Analytics. Cardiovascular: Dyslipidemia Class Management. https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Page/f6099cc7-17e0-49ce-86bc-162ec47024a5#section-group-39944. Accessed September 6, 2019.
4. Praluent (alirocumab) [prescribing information], Bridgewater, NJ: Sanofi-Aventis US LLC; April 2019.
5. Repatha (evolocumab) [prescribing information]. Thousand Oaks, CA: Amgen, February 2019.
6. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
7. USPDI, Micromedex; 2020.
8. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.