SmartPA Criteria Proposal

Drug/Drug Class: Proprotein Convertase Subtilisin Kexin type 9 (PCSK9) Inhibitors PDL Edit

First Implementation Date: January 10, 2019
Revised Date: January 6, 2022
Prepared For: MO HealthNet
Prepared By: MO HealthNet/Conduent
Criteria Status: ☒ Revision of Existing 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:

<table>
<thead>
<tr>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Praluent®</td>
<td>- N/A</td>
</tr>
<tr>
<td>- Repatha®</td>
<td></td>
</tr>
</tbody>
</table>

Type of Criteria:
- ☐ Increased risk of ADE
- ☒ Preferred Drug List
- ☒ Clinical Edit

Appropriate Indications
- ☒ 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

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
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</thead>
<tbody>
<tr>
<td>MedWatch Form:</td>
<td>Other:</td>
</tr>
</tbody>
</table>

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References