**PCSK9 Inhibitors**

**Goal(s):**
- Promote use of PCSK9 inhibitors that is consistent with medical evidence
- Promote use of high value products

**Length of Authorization:**
- Up to 12 months

**Requires PA:**
- All PCSK9 inhibitors

**Covered Alternatives:**
- Current PMPDP preferred drug list per OAR 410-121-0030 at [www.orpdl.org](http://www.orpdl.org)
- Searchable site for Oregon FFS Drug Class listed at [www.orpdl.org/drugs/](http://www.orpdl.org/drugs/)

<table>
<thead>
<tr>
<th><strong>Approval Criteria</strong></th>
<th><strong>Yes: Go to Renewal Criteria</strong></th>
<th><strong>No: Go to #2</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is this a request for the renewal of a previously approved prior authorization?</td>
<td>Record ICD10 code; go to #3</td>
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<td>2. What diagnosis is being treated?</td>
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### Approval Criteria

3. Does the patient have very high-risk clinical atherosclerotic cardiovascular disease (ASCVD), defined as documented history of multiple major ASCVD events **OR** one major ASCVD event and multiple high-risk conditions (See below)

**Major ASCVD events**
- Recent ACS (within past 12 months)
- History of MI (other than recent ACS from above)
- History of ischemic stroke
- Symptomatic peripheral artery disease

**High-Risk Conditions:**
- Age $\geq 65$
- Heterozygous familial hypercholesterolemia
- History of prior CABG or PCI
- Diabetes Mellitus
- Hypertension
- Chronic Kidney Disease
- Current smoking
- Persistently elevated LDL-C $\geq 100$ despite maximally tolerated statin therapy and ezetimibe
- History of congestive heart failure

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<tr>
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<th>Yes: Go to #4</th>
<th>No: Go to #7</th>
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</table>

4. Has the patient taken a daily high-intensity statin (see table below) and ezetimibe 10 mg daily for at least 3 months with a LDL-C still $\geq 70$ mg/dl?

Prescriber to submit chart documentation of:
1) Doses and dates initiated of statin and ezetimibe;
2) Baseline LDL-C (untreated);
3) Recent LDL-C

<table>
<thead>
<tr>
<th></th>
<th>Yes: Confirm documentation; go to #5</th>
<th>No: Go to #6</th>
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</thead>
<tbody>
<tr>
<td>1. Statin:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose:</td>
<td></td>
<td></td>
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<tr>
<td>Date Initiated:</td>
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<tr>
<td>2. Ezetimibe 10 mg daily</td>
<td>Baseline LDL-C $_____ mg/dL$</td>
<td></td>
</tr>
<tr>
<td>Date:</td>
<td>Date: $_______$</td>
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</tr>
<tr>
<td>Recent LDL-C</td>
<td>$_____ mg/dL$</td>
<td></td>
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<tr>
<td>Date: $_______$</td>
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</table>
## Approval Criteria

| 5. Is the patient adherent with a high-intensity statin and ezetimibe? | **Yes:** Approve for up to 12 months  
Note: pharmacy profile may be reviewed to verify >80% adherence (both lipid-lowering prescriptions refilled 5 months’ supply in last 6 months) | **No:** Pass to RPh; deny for medical appropriateness |
|---|---|---|
| 6. Does the patient have:  
- A history of rhabdomyolysis caused by a statin; or alternatively,  
- a history of creatinine kinase (CK) levels >10-times upper limit of normal with muscle symptoms determined to be caused by a statin; or  
- Intolerable statin-associated side effects that have been re-challenged with ≥ 2 statins | **Yes:** Confirm chart documentation of diagnosis or labs and approve for up to 12 months  
Recent LDL-C _____ mg/dL  
Date:__________ | **No:** Pass to RPh; deny for medical appropriateness |
| 7. Does the patient have a diagnosis of homozygous or heterozygous familial hypercholesterolemia? | **Yes:** Go to #8 | **No:** Pass to RPh; deny for medical appropriateness |
| 8. Does the patient still have a LDL-C of ≥ 100 mg/dl while taking a maximally tolerated statin and ezetimibe? | **Yes:** Approve for up to 12 months  
Recent LDL-C _____ mg/dL  
Date:__________ | **No:** Pass to RPh; deny for medical appropriateness |

## Renewal Criteria

| 1. What is the most recent LDL-C (within last 12 weeks)? | Recent LDL-C _____ mg/dL  
Date:__________ ; go to #2 |
Renewal Criteria

2. Is the patient adherent with PCSK9 inhibitor therapy?

| Yes: Approve for up to 12 months |
|---|---|
| Note: pharmacy profile may be reviewed to verify >80% adherence (PCSK9 inhibitor prescription refilled 10 months’ supply in last 12 months) |
| No: Pass to RPh; deny for medical appropriateness |

High- and Moderate-intensity Statins.

<table>
<thead>
<tr>
<th>High-intensity Statins (≥50% LDL-C Reduction)</th>
<th>Moderate-intensity Statins (30 to &lt;50% LDL-C Reduction)</th>
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</thead>
</table>
| Atorvastatin 40-80 mg  
Rosuvastatin 20-40 mg | Atorvastatin 10-20 mg  
Fluvastatin 80 mg  
Lovastatin 40-80 mg | Pitavastatin 1-4 mg  
Pravastatin 40-80 mg  
Simvastatin 20-40 mg  
Rosuvastatin 5-10 mg |

P&T / DUR Review: 8/21 (MH); 8/20; 5/19; 1/18; 11/16; 11/15
Implementation: 7/1/2019; 3/1/18; 1/1/1