1. **Background:**
Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member with a diagnosis of primary hyperlipidemia, heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease (ASCVD) that require additional lowering of low density lipoprotein cholesterol (LDL-C) with a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor to document the trial of maximally tolerated statin therapy prior to the use of Praluent™ (alirocumab).

Praluent (alirocumab) is a PCSK9 inhibitor antibody indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH or clinical ASCVD, who require additional lowering of LDL-C.¹

Members will be required to meet the coverage criteria below.

2. **Coverage Criteria**: 

A. **Hyperlipidemia**

1. **Praluent** will be approved based on all of the following criteria:

   a. Diagnosis of one of the following:

      (1) Primary hyperlipidemia

      (2) Heterozygous familial hypercholesterolemia

      (3) Atherosclerotic cardiovascular disease

      -AND-

   b. One of the following:

      (1) Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy and will continue to receive high-intensity statin [i.e., atorvastatin 40-80 mg, Crestor (rosuvastatin) 20-40 mg] at maximally tolerated dose

      -OR-
(2) **Both** of the following:

(a) Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN])

-AND-

(b) **One** of the following:

i. Patient has been receiving at least 12 consecutive weeks of moderate-intensity statin therapy and will continue to receive a moderate-intensity statin [i.e., atorvastatin 10-20 mg, Crestor (rosuvastatin) 5-10 mg, simvastatin ≥ 20 mg, pravastatin ≥ 40 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily or Livalo (pitavastatin) ≥ 2 mg] at maximally tolerated dose

-OR-

ii. Patient has been receiving at least 12 consecutive weeks of low-intensity statin therapy and will continue to receive a low-intensity statin [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1 mg] at maximally tolerated dose

-OR-

(3) Patient is unable to tolerate **low or moderate-**, and **high-intensity statins** as evidenced by **one** of the following:

(a) One of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN])

-OR-

(b) Patient has a labeled contraindication to all statins

-OR-

(c) Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times ULN

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c. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.

Authorization will be issued for 12 months.

B. Other Diagnoses

1. Praluent will be approved.

Authorization will be issued for 12 months.

a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Medical Necessity, Notification, and/or Supply limits may be in place.

4. References:

<table>
<thead>
<tr>
<th>Program</th>
<th>Step Therapy- Praluent™ (alirocumab)</th>
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<tbody>
<tr>
<td><strong>Change Control</strong></td>
<td></td>
</tr>
<tr>
<td>1/2016</td>
<td>New program.</td>
</tr>
<tr>
<td>7/2016</td>
<td>Added Indiana and West Virginia coverage information.</td>
</tr>
<tr>
<td>11/2016</td>
<td>Administrative change. Added California coverage information.</td>
</tr>
<tr>
<td>4/2018</td>
<td>Updated background and coverage criteria to include coverage for patients with primary hyperlipidemia. Modified previous statin requirement requiring failure, intolerance to high intensity and either moderate or low intensity statin. Removed Zetia trial requirement. Added physician attestation criterion. Updated state mandate verbiage. Updated references.</td>
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<tr>
<td>3/2019</td>
<td>Annual review with no changed to coverage criteria. Updated references.</td>
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