**Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Criteria**

**Indications:**
Alirocumab is indicated as an adjunct to diet and maximally-tolerated statin therapy for the treatment of adults with Heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density-lipoprotein cholesterol (LDL-C).

Evolicumab is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease, as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C) and as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

**Medications:**

<table>
<thead>
<tr>
<th>A. Brand Name</th>
<th>Generic Name</th>
<th>Dosage Strengths</th>
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</thead>
<tbody>
<tr>
<td>Praluent®</td>
<td>alirocumab</td>
<td>75 mg and 150 mg single use prefilled pen or syringe</td>
</tr>
<tr>
<td>Repatha™</td>
<td>evolocumab</td>
<td>140 mg prefilled autoinjector or syringe - 1, 2, and 3 packs</td>
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</tbody>
</table>

**Praluent Criterial for Approval: ALL must be met**

A. Prescriber is a cardiologist, lipidologist, or endocrinologist (or one of these specialists has been consulted), **AND**

B. Patient is 18 years of age or older, **AND**

C. Diagnosis is HeFH as confirmed by genotyping or by clinical criteria (FH using either the Simon Broome, US MedPed Program, or WHO/Dutch Lipid Network criteria), **AND**

D. Maximally-tolerated statin will continue to be used in conjunction, **AND**

E. Prior treatment history with high intensity statin (atorvastatin or rosuvastatin) **AND** one other cholesterol lowering agent (such as an alternative high intensity statin or ezetimibe) for at least 8–12 weeks with failure to reach target LDL-C (70 mg/dL for patients with clinical ASCVD)

**Repatha Criterial for Approval: ALL must be met**

A. Prescriber is a cardiologist, lipidologist, or endocrinologist (or one of these specialists has been consulted), **AND**

B. Patient is 18 years of age or older, **AND**

C. Diagnosis to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease, **OR**

D. Diagnosis is HeFH as confirmed by genotyping or by clinical criteria (FH using either the Simon Broome, US MedPed Program, or WHO/Dutch Lipid Network criteria), **OR**

E. Patient is 13 years of age or older, **AND**
F. Diagnosed with HoFH (Repatha™ only) as confirmed by either:
   – Documented DNA test for functional mutation(s) in both LDL receptor alleles or
     alleles known to affect LDL receptor functionality; OR
   – A history of an untreated LDL-C concentration > 500 mg/dL and triglycerides < 300
     mg/dL, AND

G. Prior treatment history with high intensity statin (atorvastatin or rosuvastatin) AND
   one other cholesterol lowering agent (such as an alternative high intensity statin or
   ezetimibe) for at least 8–12 weeks with failure to reach 100 mg/dL for patients with
   HeFH or HoFH and no history of clinical ASCVD

Renewal after initial 6 months for 12 months:
   A. Lipid panel showing a further reduction in LDL-C compared to the labs prior to
      initiating therapy, AND
   B. Continued adherence to maximally-tolerated statin dose established prior to the
      Praluent approval

Criteria for Denial/Renewal:
   A. Above criteria are not met, OR
   B. Failure to be compliant with current regimen as documented as no reduction in lipid
      panel, OR
   C. No claims history of atorvastatin or rosuvastatin and high intensity statin or
      ezetimibe

Length of Authorization: Initial 6 months, extended approval for 12 months if additional
   criteria are met.

Quantity Limitation:
   Praluent® – two pens/syringes per month
   Repatha™ - ASCVD or HeFH: two pens or syringes per month
   HoFH: three pens or syringes per month

References:

Available upon request.

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<thead>
<tr>
<th>Reviewed by:</th>
<th>Reason for Review:</th>
<th>Date Approved:</th>
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<tbody>
<tr>
<td>DUR Board</td>
<td>New</td>
<td>5/31/2016</td>
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<tr>
<td>Commissioner</td>
<td>Approval</td>
<td>6/18/2016</td>
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<tr>
<td>DUR Board</td>
<td>Update</td>
<td>9/27/2018</td>
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<tr>
<td>Commissioner Designee</td>
<td>Approval</td>
<td>11/27/2018</td>
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