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).

Evolocumab is indicated as an 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 or as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of 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>
</tr>
</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>
</tr>
</tbody>
</table>

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 ASCVD or HeFH as confirmed by genotyping or by clinical criteria (FH using either the Simon Broome or WHO/Dutch Lipid Network criteria), OR
D. Patient is 13 years of age or older (Repatha™ only) or patient is 18 years of age or older (Praluent® only), AND
E. Diagnosed with HoFH 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
F. Prior treatment history with highest available dose or maximally-tolerated dose of high intensity statin (atorvastatin or rosuvasat) 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 and 100 mg/dL for patients with HeFH or HoFH and no history of clinical ASCVD), AND
G. Maximally-tolerated statin will continue to be used in conjunction with evolocumab
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 original evolocumab 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:


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<thead>
<tr>
<th>Reviewed by</th>
<th>Reason for Review</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>DUR Board</td>
<td>New</td>
<td>5/31/2016</td>
</tr>
<tr>
<td>Commissioner</td>
<td>Approval</td>
<td>6/18/2016</td>
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