### Overview

Alirocumab (Praluent) and evolocumab (Repatha) are human monoclonal antibodies that bind to proprotein convertase subtilisin kexin type 9 (PCSK9). PCSK9 binds to LDL-receptors (LDLR) on the surface of hepatocytes to promote LDLR degradation in the liver. LDLR is the primary receptor that clears LDL; therefore, the decrease in LDLR levels by PCSK9 results in increased blood levels of LDL-C. By inhibiting PCSK9 binding to LDLR, these medications increase the number of LDLRs to lower LDL-C levels.

### Approvable Indications

**Praluent (alirocumab)**
1. Adjunct to diet and maximally tolerated statin therapy for the treatment of adults with Heterozygous Familial Hypercholesterolemia (HeFH)
2. Clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein (LDL)-cholesterol (LDL-C).
3. To reduce the risk of serious cardiovascular events (e.g., MI, stroke and unstable angina) requiring hospitalization in adults with established cardiovascular disease.
4. Secondary prevention of cardiovascular events: To reduce the risk of MI, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease

**Repatha (evolocumab)**
1. Homozygous familial hypercholesterolemia: Adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia who require additional lowering of LDL-C

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### Specialty Medications

<table>
<thead>
<tr>
<th>Specialty Medications</th>
<th>Phone: 866-814-5506</th>
<th>Fax: 866-249-6155</th>
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### Non-Specialty Medications

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<tr>
<td>MassHealth</td>
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<tr>
<td>Phone: 877-433-7643</td>
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<tr>
<td>Fax: 866-255-7569</td>
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<td>Commercial</td>
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<tr>
<td>Phone: 800-294-5979</td>
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<tr>
<td>Fax: 888-836-0730</td>
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<tr>
<td>Exchange</td>
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<tr>
<td>Phone: 855-582-2022</td>
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<td>Fax: 855-245-2134</td>
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### Medical Specialty Medications (NLX)

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<tr>
<td>All Plans</td>
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<td>Phone: 844-345-2803</td>
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<td>Fax: 844-851-0882</td>
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### Exceptions

N/A
2. Primary Hyperlipidemia: Adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., maximum tolerated dose of statins), for the treatment of adults with primary hyperlipidemia, including heterozygous familial hyperlipidemia, to reduce LDL-C.

3. Prevention of cardiovascular events in patients with established cardiovascular disease: To reduce the risk of MI, stroke, and coronary revascularization in adults with established cardiovascular disease

4. Add-on treatment to diet alone or together with certain other therapies for patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH).

Coverage Guidelines

**Praluent (alirocumab)**
Authorization may be granted for members who are new to AllWays Health Partners currently receiving treatment with Praluent, excluding when the product is obtained as samples or via manufacturer’s patient assistance program

OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:
1. Therapy prescribed by individuals with expertise in lipid management; this may include cardiologists, endocrinologists or primary care physicians
2. Patient is on maximal diet therapy
3. Patient is on maximum tolerated dose of high-intensity statin and ezetimibe for at least 3 months.
   Adjunctive colesevelam (Welchol) should also be considered before initiating PCSK9 inhibitors:
   a. High-intensity statin therapy is defined as a daily dose which lowers LDL cholesterol level by approximately at least 50% on average.
   b. atorvastatin, 40 to 80 mg
   c. rosuvastatin, 20 to 40 mg

**Repatha (evolocumab)**
Authorization may be granted for members who are new to AllWays Health Partners currently receiving treatment with Repatha, excluding when the product is obtained as samples or via manufacturer’s patient assistance program

OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:
1. Therapy prescribed by individuals with expertise in lipid management; this may include cardiologists, endocrinologists or primary care physicians
2. Patient is on maximal diet therapy
3. For the diagnosis of reduction in the risk of MI, stroke, and coronary revascularization in adults with established cardiovascular disease ONE of the following is required:
   a. documentation that member will use in combination with an optimized regimen of lipid-lowering therapy (e.g., high-intensity statin) is required.
   b. Lower doses are acceptable if a patient experienced adverse events and/or there is a drug interaction. Below are dose ranges for each of the medications:
      i. Atorvastatin 10 - 80 mg daily
      ii. Rosuvastatin 5 - 40 mg daily
      iii. Simvastatin 20 - 40 mg daily

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iv. Pravastatin 40 - 80 mg daily  
  v. Lovastatin 40 - 60 mg daily  
  vi. Pitavastatin 2 - 4 mg daily  
  vii. Fluvastatin 40 - 80 mg daily  
  viii. Ezetimibe 10 mg daily  

c. Absence of statin and/or ezetimibe acceptable in the setting of intolerance  
  i. Statin intolerance defined as patients experiencing intolerable adverse events on at least three statins, including alternate day dosing.  
  ii. In patients that have had clinically established rhabdomyolysis or severe CK elevation (at least 10 times the upper limit of normal), it is acceptable not to rechallenge with a statin  

4. All other diagnosis:  
  a. Patient is on maximum tolerated dose of high-intensity statin and ezetimibe for at least 3 months. Adjunctive colesvelem (Welchol) should also be considered before initiating PCSK9 inhibitors:  
    i. High-intensity statin therapy is defined as a daily dose which lowers LDL cholesterol level by approximately at least 50% on average.  
    ii. atorvastatin, 40 to 80 mg  
    iii. rosuvastatin, 20 to 40 mg  

5. Previous use of Praluent is NOT required for the diagnosis of Add-on treatment to diet alone or together with certain other therapies for patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH).  

Continuation of Therapy  
Reauthorizations require physician attestation of improvement in member’s LDL.  

Limitations  
1. Initial approvals are issued for to 3 months  
2. Reauthorizations are issued for 12 months  

References  
3. Rosenson RS. Low density lipoprotein-cholesterol (LDL-C) lowering after an acute coronary syndrome. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed December 4, 2018  
5. Repatha (evolocumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; February 2019  
Review History
12/01/15 – Implemented
09/2015 – Reviewed
09/19/16 – Reviewed
09/18/17 – Reviewed
09/24/18 – Updated
06/16/19 – Added MD attestation
09/18/19 – New indication of prevention of CV events for Praluent
12/05/19 – Removed Specialty Medication language
11/17/2021 – Reviewed and Updated for Nov P&T; Repatha moves to non-preferred for 1/1/2022 implementation. Effective 01/01/2022

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