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

Alirocumab (Praluent)

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

Evolocumab (Repatha)

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.
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

**Coverage Guidelines**

1. Authorization may be granted for members who are currently receiving treatment with Praluent or Repatha, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

   **OR**

2. PCSK9 inhibitors may be approved when physician attestation for all the following criteria is provided:
   a. Therapy prescribed by individuals with expertise in lipid management; this may include cardiologists, endocrinologists or primary care physicians
   b. Patient is on maximal diet therapy
   c. Patient is on maximum tolerated dose of high-intensity statin and ezetimibe for at least 3 months. Adjunctive colecovelam (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

3. If Repatha is to be used to reduce the risk of MI, stroke, and coronary revascularization in adults with established cardiovascular disease, documentation that member will use in combination with an optimized regimen of lipid-lowering therapy (e.g., high-intensity statin) is required.

   **OR**

   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:
   a. Atorvastatin 10 - 80 mg daily
   b. Rosuvastatin 5 - 40 mg daily
   c. Simvastatin 20 - 40 mg daily
   d. Pravastatin 40 - 80 mg daily
   e. Lovastatin 40 - 60 mg daily
   f. Pitavastatin 2 - 4 mg daily
   g. Fluvastatin 40 - 80 mg daily
   h. Ezetimibe 10 mg daily

   **OR**

   Absence of statin and/or ezetimibe acceptable in the setting of intolerance
   a. Statin intolerance defined as patients experiencing intolerable adverse events on at least three statins, including alternate day dosing.
   b. 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 re-challenge with a statin

**Continuation of Therapy**

399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org
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

**Disclaimer**

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.