Praluent (alirocumab)
Repatha (evolocumab)
Effective 02/01/2023

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

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 colesevelam (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 <u>three</u> statins, including alternate day dosing.
   b. 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

<u>Continuation of Therapy</u>

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

1. Praluent (alirocumab) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; April 2019.
2. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al; Writing Committee. 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol*. 2016;68(1):92-125
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
4. El Shahawy M, Cannon CP, Blom DJ, et al. Efficacy and safety of alirocumab versus ezetimibe over 2 years (from ODYSSEY COMBO II). *Am J Cardiol*. 2017;120(6):931-939.
5. Repatha (evolocumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; February 2019
6. Nissen SE, Stroes E, Dent-Acosta RE, et al; GAUSS-3 Investigators . Efficacy and tolerability of evolocumab vs ezetimibe in patients with muscle-related statin intolerance: the GAUSS-3 randomized clinical trial. *JAMA*. 2016;315(15):1580-1590
7. Sabatine MS, Giugliano RP, Keech AC, et al: FOURIER Steering Committee and Investigators. Evolocumab and clinical outcomes in patients with cardiovascular disease. *N Engl J Med*. 2017;376(18):1713-1722. 10.1056/NEJMoa1615664

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; separated out MH vs. Comm/Exch criteria. Effective 02/01/23

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