Mass General Brigham
Health Plan

PCSK9 Inhibitors: Repatha (evolocumab) Praluent (alirocumab) Effective 04/01/2026

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Praluent (alirocumab) and Repatha (evolumab) are proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors.

Repatha is indicated for:

- **Prevention of CV Events:** To reduce the risk of major CV events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults at increased risk for these events
- **Hypercholesterolemia:** As adjunct to diet and exercise to reduce LDL-C in adults with hypercholesterolemia
- **Heterozygous Familial Hypercholesterolemia In Patients ≥ 10 y.o.:** As an adjunct to diet and exercise to reduce LDL-C adults and pediatric patients aged 10 years and older
- **Homozygous Familial Hypercholesterolemia (HoFH) in Patients ≥ 10 y.o.:** As an adjunct to diet and exercise to reduce LDL-C in adult and pediatric patients aged 10 years and older with HoFH to reduce LDL-C

Praluent is indicated for:

- **Prevention of CV Events:** To reduce the risk of major cardiovascular events (coronary heart disease, myocardial infarction, stroke, and unstable angina requiring hospitalization) in adults at increased risk for these events
- **Hypercholesterolemia:** As adjunct to diet and exercise to reduce LDL-C in adults with hypercholesterolemia
- **Heterozygous Familial Hypercholesterolemia in Adults and Children ≥ 8 y.o.:** As an adjunct to diet and exercise to reduce LDL-C in adults and pediatric patients aged 8 years and older with HeFH to reduce LDL-C
- **Homozygous Familial Hypercholesterolemia in Adults:** As an adjunct to diet and exercise to reduce LDL-C in adults with homozygous familial hypercholesterolemia (HoFH)

Coverage Guidelines
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following diagnosis-specific criteria are met:

<u>Repatha</u>
Prevention of Cardiovascular (CV) events in members at increased risk of major CV events
1. Member is at increased risk of major cardiovascular (CV) events (e.g., death from CV disease, heart attack, stroke, certain types of chest pain conditions [including, but not limited to, unstable angina] requiring hospitalization, cardiovascular surgery)
2. ONE of the following:
    a. Member has been receiving at least 12 consecutive weeks of highest tolerable dose of statin therapy
    b. Member is statin intolerant as evidenced by inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)
    c. Member has a contraindication to all statins
    d. Member has had rhabdomyolysis with any statin
3. ONE of the following:
    a. ONE of the following within the last 120 days:
        i. Member requires greater than or equal to 25% LDL-C reduction to achieve goal
        ii. Member has LDL-C greater than or equal to 70 mg/dL
    b. BOTH of the following:
        i. Member has been receiving PCSK9 therapy
        ii. LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits

Primary Hyperlipidemia, Heterozygous Familial Hypercholesterolemia [HeFH],
1. Member meets ONE of the following:
    a. BOTH of the following:
        i. Diagnosis of heterozygous familial hypercholesterolemia (HeFH)
        ii. Member is 10 years of age or older
    b. Diagnosis of primary hyperlipidemia or hypercholesterolemia
2. ONE of the following:
    a. Member has been receiving at least 12 consecutive weeks of highest tolerable dose of statin therapy
    b. Member is statin intolerant as evidenced by inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)
    c. Member has a contraindication to all statins
    d. Member has had rhabdomyolysis with any statin
3. ONE of the following:
    a. ONE of the following while on maximally tolerated lipid-lowering therapy (e.g., statins) within the last 120 days:
        i. Member requires greater than or equal to 25% LDL-C reduction to achieve goal

ii. Member has LDL-C greater than or equal to 70 mg/dL

b. BOTH of the following:
   i. Member has been receiving PCSK9 therapy
   ii. LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits

Homozygous Familial Hypercholesterolemia

1. Diagnosis of homozygous familial hypercholesterolemia (HoFH)
2. ONE of the following:
   a. Member is receiving other lipid-lowering therapy (e.g., statin, ezetimibe)
   b. Member is unable to take other lipid-lowering therapy (e.g., statin, ezetimibe)
   c. Member has had rhabdomyolysis with any statin

Praluent

Prevention of Cardiovascular (CV) events in members at increased risk of major CV events

1. Member is at increased risk of major cardiovascular (CV) events (e.g., death from CV disease, heart attack, stroke, certain types of chest pain conditions [including, but not limited to, unstable angina] requiring hospitalization, cardiovascular surgery)
2. ONE of the following:
   a. Member has been receiving at least 12 consecutive weeks of highest tolerable dose of statin therapy
   b. Member is statin intolerant as evidenced by inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)
   c. Member has a contraindication to all statins
   d. Member has had rhabdomyolysis with any statin
3. ONE of the following:
   a. ONE of the following within the last 120 days:
      i. Member requires greater than or equal to 25% LDL-C reduction to achieve goal
      ii. Member has LDL-C greater than or equal to 70 mg/dL
   b. BOTH of the following:
      i. Member has been receiving PCSK9 therapy
      ii. LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits
4. Trial and failure, contraindication or intolerance to Repatha

Primary Hyperlipidemia, Heterozygous Familial Hypercholesterolemia (HeFH)

1. Member meets ONE of the following:
   a. BOTH of the following:
      i. Diagnosis of heterozygous familial hypercholesterolemia (HeFH)
      ii. Member is 8 years of age or older
   b. Diagnosis of primary hyperlipidemia or hypercholesterolemia
2. ONE of the following:
   a. Member has been receiving at least 12 consecutive weeks of highest tolerable dose of statin therapy
   b. Member is statin intolerant as evidenced by inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)

c. Member has contraindication to all statins
d. Member has had rhabdomyolysis with any statin

3. ONE of the following:
    a. ONE of the following while on maximally tolerated lipid-lowering therapy (e.g, statins) within the past 120 days:
        i. Member requires greater than or equal to 25% LDL-C reduction to achieve goal
        ii. Member has LDL-C greater than or equal to 70 mg/dL
    b. BOTH of the following:
        i. Member has been receiving PCSK9 therapy
        ii. LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits
4. For Members 10 years of age older: Trial and failure, contraindication, or intolerance to Repatha

Homozygous Familial Hypercholesterolemia

1. Diagnosis of homozygous familial hypercholesterolemia (HoFH)
2. ONE of the following:
    a. Member is receiving other lipid-lowering therapy (e.g., statin, ezetimibe)
    b. Member is unable to take other lipid-lowering therapy (e.g., statin, ezetimibe)
    c. Member has had rhabdomyolysis with any statin
3. Trial and failure, contraindication, or intolerance to Repatha

<u>Continuation of Therapy</u>

Requests for reauthorization will be approved when the following criteria are met:

1. Member demonstrates positive clinical response to therapy as evidenced by reduction in LDL-C levels from baseline
2. **Requests for Praluent for Members 10 Years of Age and Older:** Trial and failure, contraindication, or intolerance to Repatha

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months

References

1. 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.
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. 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
4. Praluent (alirocumab) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2025.
5. Repatha (evolocumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; August 2025.
6. 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; Repatha moves to non-preferred for 1/1/2022 implementation. Effective 01/01/2022
05/18/2022 – Reviewed and Updated for May P&T; reworded Repatha for criteria Previous use of Praluent is required except for the diagnosis of patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH).
05/14/2025 – Reviewed and updated at May P&T. Effective 09/01/2025: Updated initial criteria for primary hyperlipidemia, HeFH, and ASCVD to require diagnosis; trial and failure for at least 12 weeks with highest tolerable statin dose, intolerance to at least two statins, or contraindication to all statins; specified baseline LDL level while on statin therapy or allowing for approval if member has been on PCSK9 in adjunct with statins or ezetimibe and LDL within the past 12 months indicates the member's LDL is within normal limits. Updated criteria for HoFH to require diagnosis confirmed by either genetic mutations or untreated LDL greater than 400 mg/dL and either xanthoma before 10 y.o. or evidence of HeFH in both parents; member is taking lipid-lowering therapy or member is unable to take lipid-lowering therapy; and member is 10 years of age or older. Updated reauthorization criteria for all diagnoses to require reduction of LDL from baseline; member continues to take lipid-lowering therapy or is unable to take lipid-lowering therapy. Effective 01/01/2026:Updated criteria to prefer Repatha and updated reauthorization criteria for Praluent requests to require trial and failure with Repatha.
03/11/2026 – Reviewed and updated at March P&T. Administrative update made to language for members who are new to the Plan. Added criteria for supplemental indication of increased risk of cardiovascular disease to the policy. For initial criteria for management of primary hyperlipidemia, updated criteria for members who have been on a PCSK9 inhibitor to no longer require that they have been taking it concomitantly with a lipid-lowering agent. Removed diagnostic confirmation requirements from HoFH criteria. Updated minimum LDL for primary hyperlipidemia and HeFH to 70 mg/dL, regardless of ASCVD status. For all indications added rhabdomyolysis with any statin to the previous lipid-lowering history options. Updated reauthorization criteria to remove requirement that member continues to take other lipid-lowering therapy at maximally tolerated doses. Effective 04/01/2026.