BOSTON MEDICAL CENTER HEALTHNet PLAN

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## Pharmacy Policy

# PCSK9 Inhibitors

**Policy Number:** 9.605
**Version Number:** 2
**Version Effective Date:** 3/1/2022

| Product Applicability | ☐ **All Plan[+] Products** |
|---|---|
| **Well Sense Health Plan**<br>☐ New Hampshire Medicaid | **Boston Medical Center HealthNet Plan**<br>☒ MassHealth - MCO<br>☒ MassHealth - ACO<br>☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct<br>☐ Senior Care Options |

Note: Disclaimer and audit information is located at the end of this document.

## Prior Authorization Policy

**Products Affected:**

- **Praluent (alirocumab)**
- **Repatha (evolocumab)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

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| **Covered Use** | All FDA approved indications not otherwise excluded |
| **Exclusion Criteria** | • Member is currently taking Kynamro or Juxtapid |
| **Required Medical Information** | Documentation of the following:<br>1. A diagnosis of **primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH)** (Confirmed via genotype or using WHO/Dutch Lipid Network or Simon Broome criteria) ; AND<br>2. Current LDL-C greater than or equal to 100mg/dl; AND<br>3. Attestation of appropriate lifestyle modifications have been implemented, including an appropriate lipid-lowering diet that will continue during treatment (including but not limited to the following): |

- Total dietary fat less than 35% of total calories
- Weight loss in overweight patients
- Aerobic exercise
- Diet rich in fruits and vegetables

***OR***

A diagnosis of **homozygous familial hypercholesterolemia** (HoFH) (Confirmed via genotype or using WHO/Dutch Lipid Network or Simon Broome criteria); AND

1. One of the following:
    a. Inadequate LDL reduction while adherent to a minimum of 90 day continuous use of atorvastatin 80mg or rosuvastatin 40mg in combination with ezetimibe evidenced by:
        i. Current LDL-C greater than or equal to 100mg/dl; AND
        ii. Less than a 50 percent reduction in LDL-C from baseline; OR
    b. Inability to tolerate a high intensity statin (atorvastatin 80mg or rosuvastatin 40mg); AND Inadequate response while adherent to a minimum of 90 day continuous use of a maximum tolerated dose of a non-high intensity statin and ezetimibe evidenced by:
        i. Current LDL-C greater than or equal to 100mg/dl; AND
2. Current statin at maximum tolerated dose will be continued (Note: This may be skipped if provider attests that member is intolerant to statins); AND
3. Attestation of appropriate lifestyle modifications have been implemented, including an appropriate lipid-lowering diet that will continue during treatment (including but not limited to the following):
    - Total dietary fat less than 35% of total calories
    - Weight loss in overweight patients
    - Aerobic exercise
    - Diet rich in fruits and vegetables

***OR***

1. A diagnosis of **clinical atherosclerotic cardiovascular disease** as defined by one of the following:
    a. History of or current acute coronary syndrome
    b. Myocardial infarction
    c. Coronary or other arterial revascularization
    d. Stroke
    e. Transient ischemic stroke
    f. Stable/unstable angina
    g. Peripheral arterial disease presumed to be atherosclerotic region; AND
2. One of the following:
    a. Inadequate LDL reduction while adherent to a minimum of 90 day continuous use of atorvastatin 80mg or rosuvastatin 40mg in combination with ezetimibe evidenced by:
        i. Current LDL-C greater than or equal to 70mg/dl; OR
    b. Inability to tolerate a high intensity statin (atorvastatin 80mg or rosuvastatin 40mg); AND Inadequate response while adherent to a minimum of 90 day continuous use of a maximum tolerated dose of a non-high intensity statin and ezetimibe evidenced by:
        i. Current LDL-C greater than or equal to 70mg/dl; AND
3. Current statin at maximum tolerated dose will be continued (Note: This may be skipped if provider attests that member is intolerant to statins); AND
4. Attestation of appropriate lifestyle modifications have been implemented, including an appropriate lipid-lowering diet that will continue during treatment (including but not limited to the following):
    - Total dietary fat less than 35% of total calories

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| | • Weight loss in overweight patients<br>• Aerobic exercise<br>• Diet rich in fruits and vegetables |
| **Age Restriction** | Repatha:<br>Heterozygous familial hypercholesterolemia: 10 years and older<br>Homozygous familial hypercholesterolemia: 10 years and older<br>Atherosclerotic cardiovascular disease: 18 years and older<br><br>Praluent: 18 years and older |
| **Prescriber Restriction** | Medication is prescribed by, or in collaboration with, a cardiologist, endocrinologist, or lipid specialist |
| **Coverage Duration** | Initial: 6 months<br>Re-authorization: 12 months |
| **Other criteria** | Documentation of all the following:<br>1. Initial criteria were previously met; **AND**<br>2. Medical records documenting LDL-C reduction while on Praluent or Repatha therapy; **AND**<br>3. For diagnoses of HoFH and clinical atherosclerotic cardiovascular disease: Continued use of statin at highest tolerated dose; **AND**<br>4. Member has received counseling regarding cholesterol lowering diet. |

## Clinical Background Information and References


1. Citkowitz E. Familial Hypercholesterolemia. Medscape. Available at http://emedicine.medscape.com/article/121298-overview. Accessed on August 17, 2015.
2. Praluent (alirocumab) product information. Sanofi-Aventis U.S. LLC, Bridgewater, NJ and Regeneron Pharmaceuticals Inc, Tarrytown, NY. April 2021.
3. Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Available at https://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a.full.pdf.
4. Roth EM, Taskinen MR, Ginsberg HN et al. Monotherapy with the PSCK9 inhibitor alicrocumab versus ezetimibe in patients with hypercholesterolemia: Results of a 24 week, double-blind, randomized Phase 3 trial. International Journal of Cardiology 2014;(176):55-61.
5. Robinson JG, Farnier M, Krempf M et al. Efficacy and Safety of Alirocumab in Reducing Lipids and Cardiovascular Events. NEJM2015. Available at: NEJM.org. DOI: 10.1056/NEJMoa1501031.
6. Moriarty PM, Jacobson TA, Bruckert E et al. Efficacy and safety of alirocumab, a monoclonal antibody to PCSK9, in statin-intolerant patients: Design and rationale of ODYSSEY ALTERNATIVE, a randomized phase 3 trial. Journal of Clinical Lipidology 2014;(80):554-561.
7. Colhoun HM, Robinson JG, Farnier M et al. Efficacy and safety of alirocumab, a fully human PCSK9 monoclonal antibody, in high cardiovascular risk patients with poorly controlled hypercholesterolemia on maximally tolerated doses of statins: rationale and design of the

ODYSSEY COMBO I and II trials. BMC Cardiovascular Disorders 2014, 14:121-131.
8. Kastelein JP, Robinson JG, Farnier M et al. Efficacy and Safety of Alirocumab in Patients with Heterozygous Familial Hypercholesterolemia not Adequately Controlled with Current Lipid-Lowering Therapy: Design and Rationale of the ODYSSEY FH studies. Cardiovas Drug Ther 2014;28:281-289.
9. Repatha (evolucumab) product Information. Amgen Inc., Thousand Oaks, California. Sept 2021.

| Original Approval Date | Original Effective Date | Policy Owner | Approved by |
|---|---|---|---|
| 12/1/2020 | 1/1/2021 | Pharmacy Services | Pharmacy & Therapeutics (P&T) Committee |

| Policy Revisions History | | | |
|---|---|---|---|
| **Review Date** | **Summary of Revisions** | **Revision Effective Date** | **Approved by** |
| 12/1/2020 | 9.059 PCSK9 Inhibitors Policy retired, new policy created | 1/1/2021 | P&T Committee |
| 11/11/2021 | Updated policy to reflect updated package labeling for Repatha and Praluent: Repatha- in diagnosis of HeFH can be used without statin use, indicated for ages 10 and above. Praluent: approved for diagnosis of HoFH. Diagnoses were separated out to allow for HeFH use without statin trials. | 3/1/2022 | P&T Committee |

## Next Review Date

11/2022

## Other Applicable Policies

## Reference to Applicable Laws and Regulations, If Any

**Disclaimer Information**

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other

Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.