# PRALUENT (alirocumab)

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**Line(s) of Business:**
HMO; PPO; QUEST Integration

**Original Effective Date:**
07/01/2018
**Revision Effective Date:**
05/01/2019

**POLICY**

**A. INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication[1]

Praluent is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease, who require additional lowering of low density lipoprotein cholesterol (LDL-C).

**B. REQUIRED DOCUMENTATION**

The following information is necessary to initiate the prior authorization review:

1. Current LDL-C level for both initial requests and continuation requests. The level must be dated within the six months preceding the authorization request.
2. Chart notes confirming clinical atherosclerotic cardiovascular disease (ASCVD) if requesting Praluent to treat clinical ASCVD.
3. Chart notes confirming an LDL-receptor mutation, familial defective apo B-100, a PCSK9 gain-of-function mutation or Dutch Lipid Clinic score, familial history of cardiovascular disease, LDL-C levels or xanthomas if requesting Praluent to treat heterozygous familial hypercholesterolemia.

**C. CRITERIA FOR APPROVAL**

**1. Clinical atherosclerotic cardiovascular disease (ASCVD)**

Authorization of 6 months may be granted for treatment of clinical atherosclerotic cardiovascular disease when all of the following criteria are met:

a) Member has a history of clinical ASCVD (See Appendix A).
b) Member meets at least one of the following requirements:
   i. Member has a current LDL-C level ≥ 70 mg/dL after at least three months of treatment with a high-intensity statin dose. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
   ii. Member has a current LDL-C level ≥ 70 mg/dL with contraindication or intolerance to statins (See Appendix B and C).

**2. Heterozygous Familial Hypercholesterolemia (HeFH)**
Authorization of 6 months may be granted for treatment of heterozygous familial hypercholesterolemia when all of the following criteria are met:
a) Member has a diagnosis of familial hypercholesterolemia (See Appendix D).
b) Member meets at least one of the following requirements:
i. Member has a current LDL-C level ≥ 100 mg/dL after at least three months of treatment with a high-intensity statin dose. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
ii. Member has a current LDL-C level ≥ 100 mg/dL with contraindication or intolerance to statins (See Appendix B and C).

## D. APPENDICES

APPENDIX A. Clinical ASCVD[2,11,12]

- Acute coronary syndromes
- Myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization procedure (e.g., percutaneous coronary angioplasty [PTCA], coronary artery bypass graft [CABG] surgery)
- Stroke of presumed atherosclerotic origin
- Transient ischemic attack (TIA)
- Non-cardiac peripheral arterial disease of presumed atherosclerotic origin (e.g., carotid artery stenosis)
- Obstructive coronary artery disease (defined as fifty percent or greater stenosis on cardiac computed tomography angiogram or catheterization)

APPENDIX B. Statin-associated muscle symptoms (SAMS) and statin re-challenge[2,9]

- Intolerable SAMS persisting at least two weeks, which subsided when the medication was discontinued, and reemerged with a statin re-challenge.
  **NOTE**: Re-challenge must be with a different statin.
- Statin-associated elevation in creatine kinase (CK) level ≥ 10 times upper limit of normal (ULN)
  **NOTE**: Statin re-challenge is NOT required for members who have experienced an elevation of CK level ≥10 times ULN after receiving lipid-lowering therapy (LLT) with a statin.

APPENDIX C. Contraindications to statins

- Active liver disease, including unexplained persistent elevations in hepatic transaminase levels (e.g., alanine transaminase (ALT) level ≥ 3 times ULN)
- Women who are pregnant or may become pregnant
- Nursing mothers

APPENDIX D: Diagnosis of familial hypercholesterolemia (FH)[6,7]

A diagnosis of FH is made when one of the following diagnostic criteria is met:

- Genetic confirmation
  - An LDL-receptor mutation, familial defective apo B-100, or a PCSK9 gain-of-function mutation
- Simon-Broome Diagnostic Criteria for FH

- Total cholesterol > 290 mg/dL or LDL-C > 190 mg/dL in patients over 16 years of age or total cholesterol > 260 mg/dL or LDL-C > 155 mg/dL in patients less than 16 years of age and one of the following:
  - Tendon xanthomas in the patient, first (parent, sibling or child) or second degree relative (grandparent, uncle or aunt)
  - Family history of myocardial infarction in a first degree relative before the age of 60 or in a second degree relative before the age of 50
  - Total cholesterol greater than 290 mg/dL in an adult first or second degree relative
  - Total cholesterol greater than 260 mg/dL in a child, brother, or sister aged younger than 16 years
- Dutch Lipid Clinic Network Criteria for FH
  - Total score > 5 points

**E. CONTINUATION OF THERAPY**

Authorization of 12 months may be granted for members who achieve or maintain an LDL-C reduction (e.g., LDL-C is now at goal, robust lowering of LDL-C).

**F. DOSAGE AND ADMINISTRATION**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

**G. ADMINISTRATIVE GUIDELINES**

Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

**H. IMPORTANT REMINDER**

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes 432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/CVS's determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

**I. REFERENCES**

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8. Banach M, Rizzo M, Toth PP, et al. Statin intolerance – an attempt at a unified definition. Position paper from an International Lipid Expert Panel. *Arch Med Sci.* 2015;11:1-23.
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12. Pandor A, Ara RM, Tumur I, et al. Ezetimibe monotherapy for cholesterol lowering in 2,722 people: systematic review and meta-analysis of randomized controlled trials. *J Intern Med*. 2009 May;265(5):568-80.

**Document History**

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| 07/01/2018 | Original effective date |
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| 10/01/2018 | Annual Review- adopted enhanced SGM Hybrid |
| 05/01/2019 | Revision effective date |