SPECIALTY GUIDELINE MANAGEMENT

PRALUENT (alirocumab)

POLICY

I. 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 Indications

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

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

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

A. For initial authorization
   1. Prior and current lipid-lowering treatments and response
   2. Recent (within 90 days of the prior authorization request) cholesterol test

B. For continuation of treatment: Pretreatment and current LDL-C levels, including percentage and absolute reductions in LDL-C

III. CRITERIA FOR INITIAL APPROVAL

A. Clinical atherosclerotic cardiovascular disease (ASCVD)

Authorization of 12 months may be granted for members who meet ALL of the criteria listed below [1, 2, 3 and 4]:

1. Member is 18 years of age or older
2. Member has a history of ASCVD or cardiovascular event (See Appendix A)
3. Member meets at least ONE of the following requirements [a, b or c]:
   a. Member has a current LDL-C level ≥ 70 mg/dL after at least three months of an adherent treatment with a high-intensity statin (i.e., atorvastatin ≥ 40 mg or rosuvastatin ≥ 20 mg daily) plus ezetimibe 10 mg daily.
   b. Member has a current LDL-C level ≥ 70 mg/dL with contraindication or intolerance to statin (See Appendices B and C) and is taking ezetimibe with or without other lipid lowering medications at maximally tolerated doses or at the maximum doses approved by the FDA.
   c. Member has a current LDL-C level ≥ 70 mg/dL and contraindication to both statin and ezetimibe (See Appendix C)
4. Member’s current triglyceride is less than or equal to 400 mg/dL

B. Heterozygous Familial Hypercholesterolemia (HeFH)

Authorization of 12 months may be granted for members who meet ALL of the criteria listed below [1, 2, 3 and 4]:

1. Member is 18 years of age or older
2. Member has a definite diagnosis of familial hypercholesterolemia (See Appendix D)
3. Member meets at least ONE of the following requirements [a, b, c or d]:
   a. With ASCVD: See Section A.
b. Without ASCVD: Member has a current LDL-C level ≥ 100 mg/dL after at least three months of an adherent treatment with a high-intensity statin (i.e., atorvastatin ≥ 40 mg or rosuvastatin ≥ 20 mg daily) plus ezetimibe 10 mg daily.

c. Member has a current LDL-C level ≥ 100 mg/dL with contraindication or intolerance to statin (See Appendices B and C) and is taking ezetimibe with or without other lipid lowering medications at maximally tolerated doses or at the maximum doses approved by the FDA.

d. Member has a current LDL-C level ≥ 100 mg/dL and contraindication to both statin and ezetimibe (See Appendix C).

4. Member’s current triglyceride is less than or equal to 400 mg/dL

IV. CONTINUATION OF THERAPY

A. ASCVD

1. Authorization of 12 months may be granted for members who have received at least a three-month supply of the requested medication within the previous 120 days through a prior authorization process for a pharmacy or medical benefit and achieve or maintain an LDL-C reduction, as defined below [a, b or c]:

   a. LDL-C reduction ≥ 35%
   b. Absolute reduction in LDL-C ≥ 40 mg/dL
   c. Reduction below an LDL-C level of 70 mg/dL

2. Authorization of 12 months may be granted for members who have received at least a three-month supply of another PCSK9 inhibitor within the previous 120 days through a prior authorization process for a pharmacy or medical benefit.

B. HeFH

1. Authorization of 12 months may be granted for members without ASCVD* who have received at least a three-month supply of the requested medication within the previous 120 days through a prior authorization process for a pharmacy or medical benefit and achieve or maintain an LDL-C reduction, as defined below [a, b or c]:

   a. LDL-C reduction ≥ 35%
   b. Absolute reduction in LDL-C ≥ 40 mg/dL
   c. Reduction below an LDL-C level of 100 mg/dL

2. Authorization of 12 months may be granted for members who have received at least a three-month supply of another PCSK9 inhibitor within the previous 120 days through a prior authorization process for a pharmacy or medical benefit.

*For members with ASCVD: See Section A.

V. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The following dosing limits apply: 150 mg every 14 days.

VI. APPENDICES

APPENDIX A. Clinical ASCVD or Cardiovascular Event

- 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)
- Peripheral arterial disease of presumed atherosclerotic origin
- Findings from CT angiogram or catheterization consistent with clinical ASCVD
APPENDIX B. Statin-associated muscle symptoms (SAMS) and statin re-challenge

- Intolerable SAMS persisting at least two weeks confirmed with at least two attempts of statin re-challenge.
  **NOTE:** Re-challenges must include two different statins. One of the statins must be atorvastatin or rosuvastatin.
- Statin-associated elevation in 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 greater than or equal to 10 times ULN after receiving lipid-lowering therapy (LLT) with a statin.
- Statin-associated rhabdomyolysis (i.e., statin-associated elevation in CK level > 10,000 IU/L or significant elevation in creatinine level)
  **NOTE:** Statin re-challenge is NOT required for members who have experienced rhabdomyolysis after receiving LLT with a statin.

APPENDIX C. Contraindications to statin and ezetimibe

- 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
- Contraindication to ezetimibe
  - Hypersensitivity reactions (e.g., anaphylaxis, angioedema, rash and urticaria)

APPENDIX D: Diagnosis of familial hypercholesterolemia (FH)

A definite 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 definite FH
  - Total cholesterol > 290 mg/dL or LDL-C > 190 mg/dL, plus tendon xanthomas in the patient, first (parent, sibling or child) or second degree relative (grandparent, uncle or aunt)
- Dutch Lipid Clinic Network Criteria for definite FH
  - Total score > 8 points

VII. REFERENCES