

# ENHANCED 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

- A. Praluent is indicated to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
- B. Praluent is indicated as an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia, to reduce LDL-C.
- C. Praluent is indicated as an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

All other indications are considered experimental/investigational and not medically necessary.

#### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. Current LDL-C level for both initial requests and continuation requests. The level must be dated within the six months preceding the authorization request.
- B. Untreated (before any lipid lowering therapy) LDL-C level if requesting Praluent to treat primary hyperlipidemia, heterozygous or homozygous familial hypercholesterolemia.
- C. Chart notes confirming clinical atherosclerotic cardiovascular disease (ASCVD) if requesting Praluent to treat clinical ASCVD.
- D. If member has contraindication or intolerance to statins, chart notes confirming the contraindication or intolerance. (See Appendix B and C).

#### III. CRITERIA FOR INITIAL APPROVAL

##### **A. Clinical atherosclerotic cardiovascular disease (ASCVD)**

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

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

<b>Reference number(s)</b>
2519-A

**B. Primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH)**

Authorization of 6 months may be granted for treatment of primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH) when both of the following criteria are met:

1. Member had an untreated (before any lipid lowering therapy) LDL-C level  $\geq$  190 mg/dL in the absence of a secondary cause.
2. Member meets at least one of the following criteria:
  - a. Member has a current LDL-C level  $\geq$  100 mg/dL after at least three months of treatment with a high-intensity statin dose in combination with ezetimibe. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
  - b. Member has a current LDL-C level  $\geq$  100 mg/dL with contraindication or intolerance to statins (See Appendix B and C).

**C. Homozygous familial hypercholesterolemia (HoFH)**

Authorization of 6 months may be granted for treatment of homozygous familial hypercholesterolemia when both of the following criteria are met:

1. Member had an untreated (before any lipid lowering therapy) LDL-C level  $\geq$  190 mg/dL in the absence of a secondary cause.
2. Member meets at least one of the following criteria:
  - a. Member has a current LDL-C level  $\geq$  100 mg/dL after at least three months of treatment with a high-intensity statin dose in combination with ezetimibe. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
  - b. Member has a current LDL-C level  $\geq$  100 mg/dL with a contraindication or intolerance to statins (See Appendix B and C).

**IV. CONTINUATION OF THERAPY**

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who achieve or maintain an LDL-C reduction (e.g., LDL-C is now at goal, robust lowering of LDL-C).

**V. APPENDICES**

APPENDIX A. Clinical ASCVD

- 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, lower extremity PAD)
- Obstructive coronary artery disease (defined as fifty percent or greater stenosis on cardiac computed tomography angiogram or catheterization)
- Coronary Artery Calcium (CAC) Score  $\geq$  1000

APPENDIX B. Statin-associated muscle symptoms (SAMS) and statin re-challenge<sup>2,9,14</sup>

- Score of 7 or higher on the Statin-Associated Muscle Symptom Clinical Index (SAMS-CI)
  - Statin-associated elevation in creatine kinase (CK) level  $\geq$  10 times upper limit of normal (ULN)
- NOTE:** Statin re-challenge is NOT required for members who have experienced an elevation of CK level  $\geq$ 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  $\geq$  3 times ULN)
- Pregnancy or planned pregnancy
- Breastfeeding

## VI. REFERENCES

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