Reference number(s)
2519-A

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 (see Appendix A).
D. If member has contraindication or intolerance to statins, chart notes confirming the contraindication or intolerance (see Appendices 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:
   i. Member has a current LDL-C level ≥ 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.
   ii. Member has a current LDL-C level ≥ 70 mg/dL with contraindication or intolerance to statins (see Appendices B and C).

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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 ≥ 190 mg/dL in the absence of a secondary cause.
2. Member meets at least one of the following criteria:
   i. Member has a current LDL-C level ≥ 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.
   ii. Member has a current LDL-C level ≥ 100 mg/dL with contraindication or intolerance to statins (see Appendices 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 ≥ 190 mg/dL in the absence of a secondary cause.
2. Member meets at least one of the following criteria:
   i. Member has a current LDL-C level ≥ 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.
   ii. Member has a current LDL-C level ≥ 100 mg/dL with a contraindication or intolerance to statins (see Appendices 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 intervention [PCI], coronary artery bypass graft [CABG] surgery)
- Stroke of presumed atherosclerotic origin
- Transient ischemic attack (TIA)
- Non-cardiac peripheral arterial disease (PAD) 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 ≥ 1000

APPENDIX B. Statin-associated muscle symptoms (SAMS) and statin re-challenge
- Score of 7 or higher on the Statin-Associated Muscle Symptom Clinical Index (SAMS-CI)
- 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.

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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)
- Pregnancy or planned pregnancy
- Breastfeeding

VI. REFERENCES

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