Reference number(s)
6432-A

Custom Enhanced Supplemental Specialty PA Proprotein Convertase Subtilisin/Kexin type 9 Inhibitors (PCSK9i)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Praluent	alirocumab
Repatha	evolocumab

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 [1,2]

Praluent

- To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
- 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 (HeFH), to reduce LDL-C.

- As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 8 years and older with HeFH to reduce LDL-C.
- As an adjunct to other LDL-C-lowering therapies in adults with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

Repatha

- To reduce the risk of of major adverse cardiovasculat (CV) events (CV death, myocardial infarction, stroke, and unstable angina requiring hospitalization, or coronary revascularization) in adults with established cardiovascular disease.
- 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 (HeFH), to reduce LDL-C.
- As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C.
- An adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C.

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

Documentation

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

Initial requests:

- Chart notes confirming clinical ASCVD or ASCVD event(s) (if applicable) (see Appendix A).
- If member has contraindication or intolerance to statins, chart notes or medical record documentation confirming the contraindication or intolerance (see Appendix B).

Both initial and continuation requests:

- LDL-C level must be dated within the six months preceding the authorization request.

Coverage Criteria

Clinical atherosclerotic cardiovascular disease (ASCVD)[1-4,13]

Authorization of 12 months may be granted for treatment of clinical atherosclerotic cardiovascular disease (ASCVD) when all of the following criteria are met:

- Member has a history of clinical ASCVD (see Appendix A).

- Member meets either of the following criteria:
  - Member has a current LDL-C level ≥ 70 mg/dL.
  - Member has a current LDL-C level ≥ 55 mg/dL and has multiple ASCVD events (see Appendix A) or high-risk conditions (e.g., 65 years of age or older, familial hypercholesterolemia, diabetes, chronic kidney disease, history of congestive heart failure).
- Member meets either of the following criteria:
  - Member has received 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.
  - Member has a contraindication or intolerance to statin therapy (see Appendix B).

Primary hyperlipidemia[1-4,6]

Authorization of 12 months may be granted for treatment of primary hyperlipidemia when all of the following criteria are met:

- Member had an untreated (before any lipid-lowering therapy) LDL-C level ≥ 190 mg/dL in the absence of a secondary cause.
- Member has a current LDL-C level ≥ 100 mg/dL.
- Member meets either of the following criteria:
  - Member has received 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.
  - Member has a contraindication or intolerance to statin therapy (see Appendix B).

Heterozygous familial hypercholesterolemia (HeFH)[1-4,6]

Authorization of 12 months may be granted for treatment heterozygous familial hypercholesterolemia (HeFH) when both of the following criteria are met:

- Member meets either of the following criteria:
  - Member is 18 years of age or older and had an untreated (before any lipid-lowering therapy) LDL-C level ≥ 190 mg/dL in the absence of a secondary cause.
  - Member is less than 18 years of age and had an untreated (before any lipid-lowering therapy) LDL-C level ≥ 160 mg/dL in the absence of a secondary cause.
- Member meets either of the following criteria:
  - Member is 10 years of age or older and meets either of the following criteria:
    - 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.
    - Member has a current LDL-C level ≥ 100 mg/dL and has a contraindication or intolerance to statin therapy (see Appendix B).

- Member is 8 years of age to less than 10 years of age and the request is for Praluent, and meets either of the following criteria:
    - 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.
    - Member has a current LDL-C level ≥ 100 mg/dL and has a contraindication or intolerance to statin therapy (see Appendix B).

Homozygous familial hypercholesterolemia (HoFH)[1,2,4,7]

Authorization of 12 months may be granted for treatment of homozygous familial hypercholesterolemia (HoFH) when all of the following criteria are met:

- Member has a confirmed diagnosis of HoFH.
- Member meets either of the following criteria:
    - Member has a current LDL-C level ≥ 70 mg/dL.
    - Member has a current LDL-C level ≥ 55 mg/dL and meets either of the following criteria:
        - Member has a history of a clinical ASCVD event (see Appendix A).
        - Member has major ASCVD risk factors (e.g., 65 years of age or older, familial hypercholesterolemia, diabetes, chronic kidney disease, history of congestive heart failure).
- Member meets either of the following criteria:
    - Member is 10 years of age or older and meets either of the following criteria:
        - Member has received 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.
        - Member has a contraindication or intolerance to statin therapy (see Appendix B).
    - Member is 8 years of age to less than 10 years of age and meets either of the following criteria:
        - Member has receivd 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.
        - Member has a contraindication or intolerance to statin therapy (see Appendix B).

Primary prevention of atherosclerotic cardiovascular disease in diabetes mellitus[3,4,13]

Authorization of 12 months may be granted for primary prevention of ASCVD in members with diabetes mellitus when all of the following criteria are met:

- Member is 40 years of age to 75 years of age.
- Member has a current LDL-C level of ≥ 70 mg/dL.
- Member meets either of the following criteria:

- Member has received 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.
- Member has a contraindication or intolerance to statin therapy (see Appendix B).

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members (including new members) who have achieved or maintained an LDL-C reduction (e.g., LDL-C is now at goal, robust lowering of LDL-C).

Appendix

Appendix A. Clinical ASCVD[2,8,9,12]

- 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 ≥ 50% stenosis on cardiac computed tomography angiogram or catheterization)
- Coronary artery calcium (CAC) Score ≥ 300

Appendix B. Contraindications to statin therapy[2,10,11]

- Score of 7 or higher on the Statin-Associated Muscle Symptom Clinical Index (SAMS-CI) and failed statin rechallenge
- Presence of statin-associated muscle symptoms with elevation in creatine kinase (CK) level > 3 times upper limit of normal (ULN)
- Statin-associated elevation in creatine kinase (CK) level ≥ 10 times ULN
- 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

References

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13. American Diabetes Association Professional Practice Committee. Cardiovascular disease and risk management: standards of care in diabetes – 2024. Diabetes Care. 2024;47(Suppl 1):S179-S218.

