Reference number(s)
6432-A

CUSTOM ENHANCED SUPPLEMENTAL SPECIALTY PA

Proprotein Convertase Subtilisin/Kexin type 9 Inhibitors (PCSK9i)
PRALUENT (alirocumab), REPATHA (evolocumab)

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
   1. To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
   2. 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.
   3. 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.
   4. As an adjunct to other LDL-C-lowering therapies in adults with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

B. Repatha
   1. Adults with established cardiovascular disease to reduce the risk of myocardial infarction, stroke, and coronary revascularization.
   2. 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.
   3. 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.
   4. 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.

II. DOCUMENTATION

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

A. Initial requests:
   1. If member has contraindication or intolerance to statins, chart notes or medical record documentation confirming the contraindication or intolerance (see Appendix B).
   2. Clinical atherosclerotic cardiovascular disease (ASCVD): Chart notes confirming ASCVD (see Appendix A).
   3. Primary hyperlipidemia, heterozygous or homozygous familial hypercholesterolemia: Untreated (before any lipid-lowering therapy) LDL-C level.

B. Both initial and continuation requests: LDL-C level must be dated within the six months preceding the authorization request.

III. CRITERIA FOR INITIAL APPROVAL

A. Clinical atherosclerotic cardiovascular disease (ASCVD)

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

1. Member has a history of clinical ASCVD (see Appendix A).
2. Member meets either 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 a contraindication or intolerance to statins (see Appendix B).

B. Primary hyperlipidemia

Authorization of 12 months may be granted for treatment of primary hyperlipidemia 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 either 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 Appendix B).

C. Familial hypercholesterolemia

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

1. Member meets either of the following criteria:
    i. 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.
    ii. 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.
2. Member meets either of the following criteria:
    i. Member is 10 years of age or older and meets either of the following:
        a. 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.
        b. Member has a current LDL-C level ≥ 100 mg/dL with a contraindication or intolerance to statins (see Appendix B).
    ii. 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:
        a. 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.
        b. Member has a current LDL-C level ≥ 100 mg/dL with a contraindication or intolerance to statins (see Appendix B).

IV. 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).

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 ≥ 300

APPENDIX B. Contraindications to statin therapy

- 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

VI. REFERENCES

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