Reference number(s)
6431-A

CUSTOM 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. CRITERIA FOR INITIAL APPROVAL

A. Clinical atherosclerotic cardiovascular disease (ASCVD)
Authorization of 12 months may be granted for treatment of ASCVD when all of the following criteria are met:
   1. Member has a history of clinical atherosclerotic cardiovascular disease or has experienced a cardiovascular event.
   2. Member has a current LDL-C level ≥ 70 mg/dL.
   3. Member is receiving maximally tolerated statin therapy or has a contraindication or intolerance to statin therapy.

B. Primary hyperlipidemia

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

1. Member had an untreated (before any lipid-lowering therapy) LDL-C level ≥ 190 mg/dL.
2. Member has a current LDL-C level ≥ 100 mg/dL.
3. Member is receiving maximally tolerated statin therapy or has a contraindication or intolerance to statin therapy.

C. Familial hypercholesterolemia

Authorization of 12 months may be granted for treatment of heterozygous familial hypercholesterolemia (HeFH) or homozygous familial hypercholesterolemia (HoFH) when all 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.
   ii. Member is less than 18 years of age and had an untreated (before any lipid-lowering therapy) LDL-C level ≥ 160 mg/dL.
2. Member has a current LDL-C level ≥ 100 mg/dL.
3. Member is receiving maximally tolerated statin therapy or has a contraindication or intolerance to statin therapy.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members who are continuing therapy with a PCSK9i.

IV. REFERENCES

1. Repatha [package insert]. Thousand Oaks, CA: Amgen, Inc.; September 2021.
2. Praluent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2024.
3. Grundy SM, Stone NJ, Bailey, AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2019;139(25):e1082– e1143.
4. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2022 ACC Expert consensus decision pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: A report of the American college of cardiologic solution set oversight committee. *J Am Coll Cardiol.* 2022;80(14):1366–1418.
5. Jacobson TA, Ito MK, Maki KC, et al. National Lipid Association recommendations for patient-centered management of dyslipidemia: part 1 — full report. *J Clin Lipidol*. 2015;9:(2)129–169.
6. McGowan MP, Hosseini Dehkordi SH, Moriarty PM, et al. Diagnosis and treatment of heterozygous familial hypercholesterolemia. *J Am Heart Assoc*. 2019; 8(24):e013225.
7. Cuchel M, Raal FJ, Hegele RA, et al. Update on European atherosclerosis society consensus statement on homozygous familial hypercholesterolaemia: new treatments and clinical guidance. *Eur Heart J.* 2023;44(25):2277-2291.