BlueCross BlueShield Federal Employee Program

PRALUENT (alirocumab)

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Homozygous familial hypercholesterolemia (HoFH)
    a. 18 years of age or older
    b. Confirmed diagnosis by LDL-R DNA Sequencing Test or APOB (hypercholesterolemia) Mutation Analysis
    c. Genetic confirmation of two mutant alleles at the LDLR, Apo-B, PCSK9, ARH adaptor protein 1/LDLRAP1 gene locus
    d. Provided documentation (medical records, laboratory reports) of baseline and/or current LDL-C level ≥ 100 mg/dL in the past 6 months

2. Heterozygous familial hypercholesterolemia (HeFH)
    a. 8 years of age or older
    b. Provided documentation (medical records, laboratory reports) drawn LDL-C level ≥ 100 mg/dL in the past 6 months

    AND ONE of the following for HeFH:
    a. Confirmed diagnosis by LDL-R DNA Sequencing Test or APOB (hypercholesterolemia) Mutation Analysis
    b. Dutch Lipid Clinic Network Criteria score > 5
    c. Simon-Broome Diagnostic Criteria for definite familial hypercholesterolemia

3. Atherosclerotic cardiovascular disease (ASCVD)
    a. 18 years of age or older
    b. Provided documentation (medical records, laboratory report) of drawn LDL-C level ≥ 70 mg/dL in the past 6 months

    AND ONE of the following for ASCVD:
    a. Patient has had at least **ONE** of the following atherosclerotic cardiovascular disease (ASCVD) or cardiovascular events:
        i. Acute coronary syndrome (ACS)
        ii. Myocardial infarction (MI)
        iii. Stable or unstable angina

iv. Coronary or other arterial revascularization procedure (such as PTCA, CABG)
v. Transient ischemic attack (TIA)
vi. Peripheral arterial disease (PAD) presumed to be of atherosclerotic origin
vii. Findings from CT angiogram or catheterization consistent with clinical ASCVD

b. At high risk for atherosclerotic cardiovascular disease (ASCVD) or cardiovascular event based on 10- year risk score used by **ONE** of the following tools:
   i. ASCVD Pooled Cohort Risk Assessment score ≥ 7.5%
   ii. Predicting risk of cardiovascular disease EVENTs (PREVENT): score ≥ 7.5%

AND ALL of the following for **ALL** indications:

1. Patient will be assessed for response (i.e., LDL-C reduction) and adherence to the prescribed lipid lowering regimen after 3 months
2. Documentation of an inadequate treatment response to 3 months of at least **ONE** high intensity statin **OR** patient has an intolerance or contraindication to statin therapy
3. **NO** dual therapy with another Prior Authorization (PA) lipid lowering agent (see Appendix 1)
4. Patient **MUST** have tried the preferred product (Repatha) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior - Approval Limits

Quantity

Praluent 75mg	6 syringes per 90 days **OR**
Praluent 150mg	6 syringes per 90 days

Duration 12 months

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Homozygous familial hypercholesterolemia (HoFH)
    a. 18 years of age or older
2. Heterozygous familial hypercholesterolemia (HeFH)
    a. 8 years of age or older
3. Atherosclerotic cardiovascular disease (ASCVD)
    a. 18 years of age or older

AND ALL of the following for **ALL** indications:

1. Patient has had **ONE** of the following:
    a. Percentage reduction of LDL-C level is ≥ 40%, compared to the level immediately prior to starting a PCSK9 inhibitor
    b. Absolute LDL-C is less than < 100mg/dL
2. Patient will be assessed for adherence to the prescribed lipid lowering regimen
3. **NO** dual therapy with another Prior Authorization (PA) lipid lowering agent (see Appendix 1)
4. Patient **MUST** have tried the preferred product (Repatha) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior - Approval *Renewal* Limits

Same as above

High-Intensity Statin Therapy	Moderate-Intensity Statin Therapy	Low-Intensity Statin Therapy
Atorvastatin (Lipitor) 40 – 80 mg a day **Rosuvastatin (Crestor)** 20 – 40mg a day	**Atorvastatin (Lipitor)** 10 – 20mg a day **Rosuvastatin (Crestor)** 5 - 10mg a day **Simvastatin (Zocor)** 20 - 40mg a day	**Simvastatin (Zocor)** 10mg a day **Pravastatin (Pravachol)** 10 - 20mg a day **Lovastatin (Mevacor)** 20mg a day

	Pravastatin (Pravachol) 40 - 80mg a day **Lovastatin (Mevacor)** 40mg a day **Fluvastatin XL (Lescol XL)** 80mg a day **Fluvastatin (Lescol)** 40mg twice a day **Pitavastatin (Livalo)** 2 - 4mg a day	**Fluvastatin (Lescol)** 20 - 40mg a day **Pitavastatin (Livalo)** 1mg a day

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Appendix 1 - List of PA Lipid Lowering Agents*

Generic Name	Brand Name
alirocumab	Praluent
bempedoic acid	Nexletol
bempedoic acid/ezetimibe	Nexlizet
evolocumab	Repatha
inclisiran	Leqvio
lomitapide	Juxtapid

*Dual therapy with Evkeeza (evinacumab-dgnb) is allowed