

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

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

1. Homozygous familial hypercholesterolemia (HoFH)

AND ALL of the following for HoFH:

- a. 10 years of age and 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 drawn LDL-C level ≥ 100 mg/dL in the past 6 months

2. Heterozygous familial hypercholesterolemia (HeFH)

- a. 10 years and older
- b. Provided documentation (medical records, laboratory reports) of 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 and 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 $\geq 7.5\%$
 - ii. Predicting risk of cardiovascular disease EVENTS (PREVENT): score $\geq 7.5\%$

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)

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

| | |
|---------------|--|
| Repatha 140mg | 9 syringes or auto-injectors per 84 days OR |
| Repatha 420mg | 6 syringes per 84 days |

Duration 12 months

Prior – Approval *Renewal* Requirements



Diagnoses

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

1. Heterozygous familial hypercholesterolemia (HeFH)
 - a. 10 years of age and older
2. Homozygous familial hypercholesterolemia (HoFH)
 - a. 10 years of age and older
3. Atherosclerotic cardiovascular disease (ASCVD)
 - a. 18 years of age and older

AND ALL of the following:

- a. Patient has had **ONE** of the following:
 - i. Percentage reduction of LDL-C level is $\geq 40\%$, compared to the level immediately prior to starting a PCSK9 inhibitor
 - ii. Absolute LDL-C $< 100\text{mg/dL}$
- b. Patient will be assessed for adherence to the prescribed lipid lowering regimen
- c. **NO** dual therapy with another Prior Authorization (PA) lipid lowering agent (see Appendix 1)

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 | Atorvastatin (Lipitor) 10 – 20mg a day | Simvastatin (Zocor) 10mg a day |
| Rosuvastatin (Crestor) 20 – 40mg a day | Rosuvastatin (Crestor) 5 - 10mg a day | Pravastatin (Pravachol) 10 - 20mg a day |
| | Simvastatin (Zocor) 20 - 40mg a day | Lovastatin (Mevacor) 20mg a day |



**REPATHA
(evolocumab)**

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

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