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:
   a. 13 years and older
   b. Provided documentation (medical records, patient’s chart) of 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 90 days

2. **Heterozygous familial hypercholesterolemia (HeFH)**
   a. 18 years and older
   b. Provided documentation (medical records, laboratory reports) of baseline and/or current LDL-C level ≥ 100 mg/dL in the past 90 days

   **AND ONE** of the following:
   1) Provided documentation (medical records, patient’s chart) of confirmed diagnosis by LDL-R DNA Sequencing Test or APOB (hypercholesterolemia) Mutation Analysis
   2) Dutch Lipid Clinic Network Criteria score > 5
   3) Simon-Broome Diagnostic Criteria for definite familial hypercholesterolemia

3. **Atherosclerotic cardiovascular disease (ASCVD)**
   a. 18 years and older
   b. Laboratory report or medical records of LDL-C 70 mg/dL or greater in the past 90 days

   **AND ONE** of the following for ASCVD:
a. Documented history of ONE of the following atherosclerotic cardiovascular disease (ASCVD) or cardiovascular events:
   i. Acute coronary syndrome
   ii. Myocardial infarction
   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 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 greater than or equal to 7.5%
   ii. Framingham Risk Score—score greater than or equal to 20%

AND ALL of the following for ALL diagnoses:
1. Patient will be assessed for response (ie., LDL-C reduction) and adherence to the prescribed lipid lowering regiment after 3 months
2. NO dual therapy with another proprotein convertase subtilisin/kexin type 9 inhibitor, Juxtapid

AND ONE of the following for ALL diagnoses:
1. Inadequate response to 3 months of prior therapy with at least ONE trial of a high intensity statin in combination with Zetia (ezetimibe)
2. Intolerance to a statin
   a. Provide medical records of documentation of the following intolerable adverse reactions with ONE of the following:
      i. Intolerable and persistent (ie: more than 2 weeks) muscle symptoms (eg., muscle pain, weakness, cramps) with ONE of the following:
         1) Myalgia (muscle symptoms without CK elevations) – Patient has undergone prior therapy with at least TWO trials of different statins with or without Zetia (ezetimibe) with a documented reappearance of the muscle symptoms
2) Myositis (muscle symptoms with CK elevations) – Documentation provided indicated creatinine kinase (CK) levels greater than 3 times upper normal limit and/or rhabdomyolysis with CK levels greater than 2,500 IU/L

b. Intolerable and persistent hepatotoxicity after TWO trials of different statins with or without Zetia (ezetimibe) with ALL of the following:
   i. Documentation indicating persistent elevations (>3 times the upper limit of normal occurring on 2 more occasions) of serum transaminases or the presence of jaundice
   ii. Secondary causes of elevations in hepatic transaminase levels have been ruled out (e.g., infection, medications, herbal supplements)

3. Contraindication to a statin must have ONE of the following:
   a. Currently pregnant or may become pregnant
   b. Nursing mother

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

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Repatha 140mg</td>
<td>9 syringes per 90 days OR</td>
</tr>
<tr>
<td>420mg</td>
<td>3 syringes per 90 days</td>
</tr>
</tbody>
</table>

Duration 12 months

Prior – Approval Renewal Requirements

Diagnoses

Patient must have ONE of the following:

1. Heterozygous familial hypercholesterolemia (HeFH)
2. Homozygous familial hypercholesterolemia (HoFH)
3. Atherosclerotic cardiovascular disease (ASCVD)

AND ALL of the following:
1. Documentation has been provided indicating the reduction in LDL-C (i.e., chart notes, medical record, and/or laboratory reports) of ONE of the following:
   a. Percentage reduction of LDL-C level is greater than or equal to (≥) 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 proprotein convertase subtilisin/kexin type 9 inhibitor, Juxtapid

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.

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<table>
<thead>
<tr>
<th>High-intensity statin therapy</th>
<th>Moderate-intensity statin therapy</th>
<th>Low-intensity statin therapy</th>
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<tbody>
<tr>
<td>Atorvastatin (Lipitor) 40 - 80 mg a day</td>
<td>Atorvastatin (Lipitor) 10 - 20mg a day</td>
<td>Simvastatin (Zocor) 10mg a day</td>
</tr>
<tr>
<td>Rosuvastatin (Crestor) 20 - 40mg a day</td>
<td>Rosuvastatin (Crestor) 5 - 10mg a day</td>
<td>Pravastatin (Pravachol) 10 - 20mg a day</td>
</tr>
<tr>
<td>Simvastatin (Zocor) 80mg a day</td>
<td>Simvastatin (Zocor) 20 - 40mg a day</td>
<td>Lovastatin (Mevacor) 20mg a day</td>
</tr>
<tr>
<td>Lovastatin (Mevacor) 40mg a day</td>
<td>Lovastatin (Mevacor) 40 - 80mg a day</td>
<td>Fluvastatin (Lescol) 20 - 40mg a day</td>
</tr>
<tr>
<td>Fluvastatin XL (Lescol XL) 80mg a day</td>
<td>Fluvastatin (Lescol) 40mg twice a day</td>
<td>Pitavastatin (Livalo) 2 - 4mg a day</td>
</tr>
<tr>
<td>Pitavastatin (Livalo) 80mg a day</td>
<td>Pitavastatin (Livalo) 40mg a day</td>
<td>Pitavastatin (Livalo) 1mg a day</td>
</tr>
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Repatha FEP Clinical Criteria