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*Drug Class Prior Authorization Criteria*  
**Proprotein Convertase Subtilisin/Kexin Type 9  
(PCSK9) Inhibitor**

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**Line of Business:** Medicaid

**P & T Approval Date:** May 7, 2021

**Effective Date:** May 7, 2021

*This drug class prior authorization criteria have been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.*

**Drugs Requiring Prior Authorization Review: Repatha (evolocumab)**

**CRITERIA:**

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**REPATHA (EVOLOCUMAB)**

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**Covered Uses:**

- \*Homozygous Familial Hypercholesterolemia
- \*Heterozygous Familial Hypercholesterolemia
- (\*Subject to review by Clinical Pharmacist)

**Exclusion Criteria:**

CCS eligible

**Required Medical Information:**

Must meet all of the following requirements:

- a. Familial hypercholesterolemia (FH) as established by “1” of the following:
  - i. Presence of a mutation in LDLR, apolipoprotein B (ApoB), PCSK9, or ARH adaptor protein (LDLRAP1) gene.
  - ii. Pre-treatment LDL level greater than 190 mg per dL or total cholesterol greater than 290 mg per dL in an adult or pre-treatment LDL level greater than 155 mg per dL or total cholesterol greater than 250 mg per dL in a child and tendon xanthomas in patient or a first-or-second-degree relative.
- b. Medical record documentation (e.g. chart notes) indicating “1” of the following:
  - i. Patient has been adherent for 3 consecutive months of high-intensity statin therapy (e.g. atorvastatin 40 mg or higher, rosuvastatin 20 mg or higher) and will continue to receive the maximally tolerated dose.

- ii. Patient is unable to tolerate high-intensity statin due to documented myalgia or myositis, but patient has been adherent for 3 consecutive months of the maximally tolerated statin therapy (e.g. atorvastatin, lovastatin, pravastatin, rosuvastatin, or simvastatin at any dose) and will continue to receive the maximally tolerated dose.
  - iii. Patient has a labeled contraindication to all statins as documented in medical records.
  - iv. Patient is not on statin due to documented rhabdomyolysis or muscle symptoms with CK elevations greater than or equal to 10 times ULN.
- c. Medical record documentation (e.g. chart notes) indicating “1” of the following:
- i. Patient has been adherent for 3 consecutive months of ezetimibe, concurrently with statin per criteria b.
  - ii. Patient has a labeled contraindication or intolerance to ezetimibe.
- d. Documentation indicating “1” of the following treated LDL levels while on optimal lipid lowering therapy (maximally tolerated statin and ezetimibe therapy), dated within the last month (30 days):
- i. LDL greater than or equal to 70 mg per dL with ASCVD.
  - ii. LDL greater than or equal to 100 mg per dL without ASCVD.
- e. Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor, **Juxtapid** or **Kynamro**

**Age Restrictions:** Must be age of 13 years or older

**Prescriber Restrictions:** Cardiologist, Endocrinologist or Lipid Specialist

**Other Criteria:** Reauthorization criteria: Must meet all of the following requirements:

- a. Patient is adherent to therapy since the initial authorization.
- b. Patient continues concurrent use of the high-intensity statin or the statin at the maximally tolerated dose, unless documentation of the inability to take statins is provided.
- c. Documentation of LDL reduction while on **Repatha** therapy.

**Covered Uses:** \*Atherosclerotic Cardiovascular Disease  
(\*Subject to review by Clinical Pharmacist)

**Exclusion Criteria:** N/A

**Required Medical Information:** Must meet all of the following requirements:

- a. Documentation of “1” of the following:
  - i. History of at least “2” major atherosclerotic cardiovascular disease events: recent acute coronary syndrome (within the

- past 12 months), myocardial infarction (MI), ischemic stroke or symptomatic peripheral disease
  - ii. History of “1” major atherosclerotic cardiovascular disease event: recent acute coronary syndrome (within the past 12 months), myocardial infarction (MI), ischemic stroke or symptomatic peripheral disease; **and** at least “2” of the following high-risk conditions: age of 65 years or older, familial hypercholesterolemia (homozygous or heterozygous), history of prior coronary artery bypass surgery or percutaneous coronary intervention, diabetes mellitus, hypertension, chronic kidney disease, current smoking, persistently elevated LDL of 100 mg/dL or greater despite optimal lipid therapy, or history of congestive heart failure
- b. Medical record documentation (e.g. chart notes) indicating “1” of the following:
  - i. Patient has been adherent for 3 consecutive months of high-intensity statin therapy (e.g. atorvastatin 40 mg or higher, rosuvastatin 20 mg or higher) and will continue to receive the maximally tolerated dose.
  - ii. Patient is unable to tolerate high-intensity statin due to documented myalgia or myositis, but patient has been adherent for 3 consecutive months of the maximally tolerated statin therapy (e.g. atorvastatin, lovastatin, pravastatin, rosuvastatin, or simvastatin at any dose) and will continue to receive the maximally tolerated dose.
  - iii. Patient has a labeled contraindication to all statins as documented in medical records.
  - iv. Patient is not on statin due to documented rhabdomyolysis or muscle symptoms with CK elevations greater than or equal to 10 times ULN.
- c. Medical record documentation (e.g. chart notes) indicating “1” of the following:
  - i. Patient has been adherent for 3 consecutive months of ezetimibe, concurrently with statin per criteria b.
  - ii. Patient has a labeled contraindication or intolerance to ezetimibe.
- d. Documentation indicating “1” of the following treated lipid levels while on optimal lipid lowering therapy (maximally tolerated statin and ezetimibe therapy), dated within the last month (30 days):
  - i. LDL greater than or equal to 70 mg per dL
  - ii. Non-HDL greater than or equal to 100 mg per dL
- e. Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor, **Juxtapid** or **Kynamro**.

**Age Restrictions:** Must be age of 18 years or older

**Prescriber Restrictions:** Cardiologist, Endocrinologist or Lipid Specialist

**Other Criteria:**

Reauthorization criteria: Must meet all of the following requirements:

- a. Patient is adherent to therapy since the initial authorization.
- b. Patient continues concurrent use of the high-intensity statin or the statin at the maximally tolerated dose, unless documentation of the inability to take statins is provided.
- c. Documentation of LDL reduction while on **Repatha** therapy.

Change Control		
Date	Change	RPH
04/16/2021	<ul style="list-style-type: none"> <li>• Renew with no changes</li> </ul>	JM
02/19/2020	<ul style="list-style-type: none"> <li>• Retired PA criteria for <b>Praluent</b> (alirocumab)</li> <li>• Added homozygous familial hypercholesterolemia as one of the high-risk conditions under atherosclerotic cardiovascular disease indication under <b>Repatha</b> (evolocumab) criteria</li> </ul>	SV
02/20/2019	<p>Updated criteria per 2018 AHA/ACC guideline on management of blood cholesterol:</p> <ul style="list-style-type: none"> <li>• Clinical atherosclerotic cardiovascular disease:               <ol style="list-style-type: none"> <li>a. Documentation of very high risk ASCVD including history of multiple major ASCVD events or 1 major ASCVD event with multiple high-risk conditions</li> <li>b. Treated LDL <math>\geq</math> 70 or non-HDL <math>\geq</math> 100 on maximal statin and ezetimibe therapy</li> </ol> </li> <li>• Familial hypercholesterolemia:               <ol style="list-style-type: none"> <li>a. Treated LDL <math>\geq</math> 70 with ASCVD or LDL <math>\geq</math> 100 without ASCVD on maximal statin and ezetimibe therapy</li> </ol> </li> <li>• <b>Repatha</b> is the preferred, formulary PCSK9 product</li> </ul>	HC/ND
06/29/2018	<ul style="list-style-type: none"> <li>• Changed Format</li> </ul>	IK
02/21/2018	<ul style="list-style-type: none"> <li>• Added quantity limit</li> <li>• Updated guidance of 2017 American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Dyslipidemia and Prevention of Cardiovascular Disease</li> </ul>	CT