PriorityHealth

Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☒ **Commercial (Traditional)** ☒ **Commercial (Individual/Optimized)** ☐ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Repatha™ (evolocumab)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____

Provider Address: _____

Provider NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

What is the provider's specialty? ☐ Cardiologist ☐ Endocrinologist ☐ Lipidologist ☐ Other: _____

Product Information

☐ New request ☐ Continuation request

Drug product:

☐ Repatha 140 mg SureClick autoinjector (NDC 72511-0760-02)

☐ Repatha 140 mg syringe (NDC 72511-0750-01)

☐ Repatha 420 mg/3.5 ml Pushtronix (NDC 72511-0770-01)

Start date (or date of next dose): _____

Date of last dose (if applicable): _____

Dose: _____

Frequency: _____

EVOLOCUMAB COVERAGE POLICY

Before this drug is covered, the patient must meet all of the requirements in sections I and II or I and III:

I. Patient is at high risk for Acute Coronary Syndrome (ACS) due to **one** of the following:
   a. Diagnosis of **Homozygous Familial Hypercholesterolemia (HoFH)** confirmed by **one or more** of the following:
      i. Presence of two mutant alleles at the LDL receptor, Apolipoprotein B, or PCSK9 gene; **or**
      ii. An untreated LDL-C greater than 500 mg/dL (13 mml/L) before treatment or greater than 300 mg/dL (7.76 mmol/L) despite treatment, **and** either have cutaneous or tendinous xanthoma before age 10 years or untreated LDL-C levels consistent with heterozygous familiar hypercholesterolemia in both parents (greater than 190 mg/dL)

   b. Diagnosis of **Heterozygous familial hypercholesterolemia (HeFH)** confirmed by **one or more** of the following:
      i. Genetic testing; **or**
      ii. Score of "Definite Familial Hypercholesterolemia" on the Simon-Broome criteria; **or**
      iii. Score greater than 8 based on the WHO Dutch Lipid Clinic Network diagnostic criteria

   c. Diagnosis of **very high risk** clinical **atherosclerotic cardiovascular disease (ASCVD)** defined by the 2018 AHA/ACC Guideline on the Management of Blood Cholesterol (refer to table below). Very high-risk includes a history of multiple major ASCVD events or one major ASCVD event and multiple high-risk conditions.

All fields must be complete and legible for review. Your office will receive a response via fax. No changes made since 11/2018

Last reviewed 11/2018

II. Patient with an approved diagnosis above must also meet **all** of the following:
   a. Repatha is prescribed by a cardiologist, endocrinologist, or board-certified lipidologist; **and**
   b. Must submit most recent LDL-C laboratory report; **and**
   c. Must continue to receive maximally tolerated statin therapy or have a contraindication to statin therapy; **and**
   d. Must not use in combination with Juxtapid (lomitapide), Kynamro (mipomersen), or Praluent (evolocumab); **and**
   e. Requires documentation of compliant use with at least one high-intensity statin (rosuvastatin ≥ 20 mg daily or atorvastatin ≥ 40 mg daily) in combination with ezetimibe for at least 8 consecutive weeks with failure to achieve LDL-C < 70 mg/dL in patients with history of CVD or LDL-C < 100 mg/dL in patients without history of CVD.

III. Coverage for statin intolerance requires **all** of the following:
   a. Must meet criteria listed above under section II., lines a.- d.; **and**
   b. Trial of at least 3 different statins*, one of which must be a non-daily, long-acting statin dosing regimen (i.e. rosuvastatin every-other-day), as well as a low-moderate intensity statin trial if high-intensity is not tolerated; **and**
   c. Medical records documenting that intolerable skeletal-muscle related symptoms to each statin trialed resolve upon statin discontinuation, and are reproducible by statin re-challenge; **and**
   d. Statin intolerance/symptoms are not attributable to drug interactions, concurrent illness, underlying muscle disease, or significant changes in physical activity; **and**
   e. Unable to achieve LDL-C < 70 mg/dL in patients with history of CVD or LDL-C < 100 mg/dL in patients without history of CVD, despite treatment with maximally tolerated statin dose in combination with ezetimibe for at least 8 consecutive weeks (if unable tolerate any statin dose, trial required with ezetimibe monotherapy).

*If patient experiences statin-associated rhabdomyolysis, no further statin trials are required.

Table 1. Very High-Risk (history of multiple major ASCVD events or one major ASCVD event and multiple high-risk conditions) of future ASCVD Events

Major ASCVD Events
Recent ACS (within the past 12 mo)
History of MI (other than recent ACS event listed above)
History of ischemic stroke
Symptomatic peripheral arterial disease (history of claudication with ABI <0.85, or previous revascularization or amputation (S4.1-39))
High-Risk Conditions
Age ≥65 y
Heterozygous familial hypercholesterolemia
History of prior coronary artery bypass surgery or percutaneous coronary intervention outside of the major ASCVD event(s)
Diabetes mellitus
Hypertension
CKD (eGFR 15-59 mL/min/1.73 m_2) (S4.1-15, S4.1-17)
Current smoking
Persistently elevated LDL-C (LDL-C ≥100 mg/dL [≥2.6 mmol/L]) despite maximally tolerated statin therapy and ezetimibe
History of congestive HF

Reference: 2018 ACC/AHA/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 Foundation/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2018;Nov 10

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

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PriorityHealth

New request
Priority Health Precertification Documentation

A. What condition is this drug being requested for?

☐ Homozygous Familial Hypercholesterolemia (HoFH)
☐ Heterozygous familial hypercholesterolemia (HeFH)
☐ Very high risk clinical atherosclerotic cardiovascular disease (ASCVD)
☐ Other – the patient's condition is: _____
Rationale for use: _____

B. If homozygous familial hypercholesterolemia, does the patient have genetic testing to support the diagnosis?

☐ Yes (must submit to Priority Health)
☐ No – *rationale for use*: _____

C. If heterozygous familial hypercholesterolemia, does the patient have either of the below to support the diagnosis?

☐ Genetic testing (must submit to Priority Health)
☐ WHO Dutch Lipid Clinic Network diagnostic score of 8 or higher (complete table below by circling applicable values)
☐ Simon-Broome criteria for Familial Hypercholesterolemia (must submit to Priority Health)
☐ None – *rationale for use*: _____

	Criteria	Score
Family History	First-degree relative known with premature CAD and/or first-degree relative with LDL-C > 95th percentile	1
	First-degree relative with tendon xanthomata and/or children <18 with LDL-C >95th percentile	2
Clinical History	Patient has premature CAD	2
	Patient has premature cerebral/peripheral vascular disease	1
Physical Examination	Tendon xanthomata	6
	Arcus cornealis below the age of 45 years	4
LDL-C	> 330 mg/dL	8
	250 – 329 mg/dL	5
	190 – 249 mg/dL	3
	155 – 189 mg/dL	1
	Total score:	

D. If ASCVD, what conditions makes this patient very high risk (refer to table 1): _____

_____

E. Please provide details of medication history and lab values below (include baseline LDL-C if available).

LDL-C value (date of lab)	Medication(s) & dose(s)	Dates drug(s) used	Reason for stopping

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F. If approved for Repatha, will the patient continue to receive a high-intensity statin therapy (atorvastatin or rosuvastatin) or statin therapy at the maximally tolerated dose?

☐ Yes
☐ No, *rationale:* _____

G. If request is for statin-intolerance:

a. Did symptoms resolve upon statin discontinuation and return with statin re-challenge?

☐ Yes (please provide documentation)
☐ No, *rationale:* _____

b. Were drug interactions, concurrent illness, underlying muscle disease, or significant changes in physical activity assessed as possible causes for patient's symptoms?

☐ Yes
☐ No, *rationale:* _____

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