Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

REPATHA® (*evolocumab*) PA CRITERIA:

REPATHA® (*evolocumab*) is a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor indicated:

- To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults with established cardiovascular disease.
- As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C.
- As an adjunct to diet and other LDL-C lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C.
- As an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C.

Prior authorization is required for REPATHA®. Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation (e.g., chart notes, lab results, etc.).

<u>Initial Authorization</u>: 12 Months

1. Age of the patient is within the age range as recommended by the FDA label.

   -AND-

2. Documented diagnosis of ONE of the following:
   a. Established Atherosclerotic Cardiovascular Disease (ASCVD)
      i. Clinical ASCVD includes acute coronary syndrome (ACS), those with history of myocardial infarction (MI), stable or unstable angina or coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), or peripheral artery disease (PAD) including aortic aneurysm, all of atherosclerotic origin.

   -OR-

   b. Homozygous Familial Hypercholesterolemia (HoFH) as evidenced by:
      i. Genetic confirmation of two mutant alleles at the LDL receptor, ApoB, PCSK9, or LDLRAP1 gene locus or ARH adaptor protein gene locus**; or**
      ii. An untreated LDL-C > 500 mg/dL with either:
         1. Cutaneous or tendon xanthoma before age 10 years**; or**
         2. Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (≥190 mg/dL)

   -OR-

c. Severe Primary Hypercholesterolemia (including heterozygous familial hypercholesterolemia (HeFH), untreated LDL-C ≥ 190 mg/dL, at high risk for ASCVD defined as a 10-year ASCVD risk percent of ≥ 20% with LDL-C 70 to 189 mg/dL or patients 40 – 75 years of age with diabetes and 10-year ASCVD risk > 7.5%)
    i. Diagnosis of HeFH as evidenced by one of the following:
        1. Functional mutation in the LDLR, ApoB, PCSK9, or ARH adaptor protein (LDLRAP1) gene**; or**
        2. Corneal arcus (seen in ages < 45 years), xanthelasma (seen in ages < 25 years), or tendon xanthomas**; or**
        3. Clinical diagnosis based on the World Health Organization Dutch Lipid Clinical Network criteria with a "probable familial hypercholesterolemia" score of ≥ 6 points or definite diagnosis by Simon Broom criteria

-AND-

3. Documentation of recent (within the last 30 days) LDL-C of one of the following despite maximally tolerated lipid-lowering therapy:
    a. LDL-C ≥ 55 mg/dL AND Very High Risk ASCVD (defined as a history of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions)**; or**
    b. LDL-C ≥ 70 mg/dL for patients with clinical ASCVD AND not at very high risk**; or**
    c. LDL-C ≥ 100 mg/dL (or LDL ≥ 70 mg/dL for patients 40 to 75 years of age with diabetes) for severe primary hypercholesteremia (including HeFH) without ASCVD but with multiple risk factors that increase subsequent risk of ASCVD

-AND-

4. Adherence (defined as 85% by consistent pharmacy claims) to a high intensity statin regimen for at least 12 weeks or to a moderate-intensity statin for at least 12 weeks if unable to tolerate a high-intensity statin, unless one of the following applies:
    a. Statin therapy is contraindicated**; or**
    b. Documented statin risk factors**; or**
    c. Rhabdomyolysis or muscle symptoms with statin treatment with CK elevations**; or**
    d. Statin intolerance due to:
        i. Myopathy: Unexplained muscle pain or weakness accompanied by CK elevations**; or**
        ii. Myalgia: Muscle symptoms without CK elevations and meets both of the following:
            1. Intolerable statin associated muscle symptoms (SAMS) persisting for at least two weeks which disappeared with discontinuation of the statin therapy and recurred with a statin re-challenge**; and**
            2. Intolerant despite re-challenge with titration from the lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly)

- AND-

5. Adherence (defined as 85% by consistent pharmacy claims) to Zetia (ezetimibe) therapy used concomitantly with a statin at the maximally tolerated dose over the past 12 weeks, unless one of the following applies:
    a. Zetia therapy is contraindicated**; or**
    b. History of Zetia intolerance (e.g. associated diarrhea or upper respiratory tract infection)**; or**
    c. If ≥ 15% LDL-C reduction is required despite adherence with statin therapy, use of Zetia is not required.

-AND-

6. Repatha will be used concomitantly with a maximally tolerated statin and Zetia unless contraindications, intolerance, or the use of Zetia is not required.

-AND-

7. Repatha will not be used in combination with Juxtapid (lomitapide) or another PCSK9 inhibitor.

Re-Authorization: 12 Months

1. Evidence of adherence (defined as 85% consistent pharmacy claims) to ongoing concomitant lipid lowering therapy as applicable.

-AND-

2. Lab results obtained within the last 12 weeks show an LDL-C reduction since the initiation of Repatha therapy.

REPATHA® (*evolocumab*) Dosing:

Indication	Recommended Dosage
Adults with Established Cardiovascular Disease or with Primary Hyperlipidemia OR Patients Aged 10 Years and Older with HeFH	140 mg every 2 weeks OR 420 mg once monthly
Adults and Pediatric Patients Aged 10 Years and Older with HoFH	420 mg once monthly. The dosage can be increased to 420 mg every 2 weeks if a clinically meaningful response is not achieved in 12 weeks. Patients on lipid apheresis may initiate treatment with 420 mg every 2 weeks to correspond with apheresis schedule.

REPATHA® (*evolocumab*) Formulation:

- REPATHA® is available as:
    - 140 mg/mL solution prefilled single-dose SureClick® autoinjector
    - 140 mg/mL solution prefilled single-dose syringe
    - 420 mg/3.5 mL solution single-dose Pushtronex® system (on-body infusor with prefilled cartridge)