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 at increased risk for these events.
- As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in:
  - adults with hypercholesterolemia.
  - adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH).
  - adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH).

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. Severe primary hypercholesterolemia with LDL-C ≥190 mg/dL

   -OR-

   b. At high risk for major adverse CV events, defined as 10-year ASCVD risk percent of ≥ 20%

   -OR-

   c. 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-

d. HeFH as evidenced by one of the following:
    i. Functional mutation in the LDLR, ApoB, PCSK9, or ARH adaptor protein (LDLRAP1) gene**; or**
    ii. Corneal arcus (seen in ages < 45 years), xanthelasma (seen in ages < 25 years), or tendon xanthomas**; or**
    iii. 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 creatine kinase (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 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 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
CV risk reduction or hypercholesterolemia or HeFH	140 mg every 2 weeks OR 420 mg once monthly
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)