

PRIOR AUTHORIZATION DESCRIPTION



Background information:

Per the 2018 ACC/AHA national cholesterol treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, repeated every 3 to 12 months as needed.

For primary prevention in patients with LDL-C of 190mg/dL or higher, high-intensity statin therapy is recommended to reduce LDL-C by more than 50% and to less than 100 mg/dL.

- High-risk patients should initiate statin therapy with a goal of more than 50% LDL-C reduction.
- Patients aged 40 to 75 years who also have diabetes and LDL-C of 70 mg/dL or higher should receive moderate-intensity statin therapy.

For primary prevention in all other patients aged 40 to 75 years, the decision to actively treat lipids is largely based on the updated ASCVD Risk Estimator Plus. Access to 10-year ASCVD risk estimator:

- <http://www.acc.org/ASCVDApp>;

Note: ACVD Risk Estimator Plus provides sex and race specific equations for 4 groups: white men, white women, black men, black women; uncertain utility in other racial/ ethnic groups. For individuals outside this age range, simultaneous 10-year and life-time risk assessment is reasonable for clinician/individual patient discussions.

10-year risk for ASCVD is categorized as:

- Low risk= < 5% over 10 years, borderline risk = 5% - 7.4%, intermediate risk= 7.5% -19.9%, high risk= \geq 20%
 - ✓ Patients with high risk of ASCVD include the following:
 - History of clinical atherosclerotic cardiovascular disease
 - Diabetes with an estimated 10-year ASCVD risk \geq 7.5% for adults 40-75 years of age
 - Untreated LDL \geq 190 mg/dL
 - ✓ Patients with moderate risk of ASCVD include the following:
 - Diabetes with an estimated 10-year ASCVD risk < 7.5% for adults 40-75 years of age
 - Estimated 10-year ASCVD risk \geq 5% for adults 40-75 years of age

Clinical ASCVD: Pharmacologic lipid management is strongly recommended, even without risk calculation, in patients with clinical ASCVD. Stratified LDL-C goals have been reintroduced for patients with clinical ASCVD.

- First, reduce LDL-C by greater than 50% using high-intensity statins.
- Reduction of LDL-C level to target is a secondary goal after reduction of LDL-C percentage is achieved.
- Patients with very high risk ASCVD have a second goal of reducing LDL-C to less than 70 mg/dL. If this cannot be achieved with a high intensity statin, ezetimibe or a PCSK9 inhibitor (alirocumab/evolocumab) is recommended.
- ✓ Very high-risk includes:
 - History of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions.

Clinical Atherosclerotic Cardiovascular Disease (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.

- Reference: Circulation 2019;139:e1082–e1143. DOI: 10.1161/CIR.0000000000000625 <https://www.ahajournals.org/doi/10.1161/CIR.0000000000000624>

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CRITERIA/ADDITIONAL DOCUMENTATION

REPATHA™ (evolocumab)



BENEFICIARY INFORMATION	
Beneficiary ID: _____ - _____ - _____	DOB: ____/____/____
Beneficiary Full Name:	
<p>REPATHA is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated:</p> <ul style="list-style-type: none"> • to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease • as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C) • as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C 	
REPATHA™ (Evolocumab)	
INITIAL AUTHORIZATION CRITERIA: May be approved when the below criteria are met: (12 weeks approval duration)	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Age of patient is within the age range as recommended by the FDA label;
AND	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Prescribed by or in consultation with a cardiologist, endocrinologist or lipid specialist;
AND	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Diagnosis of one of the following:
1) <input type="checkbox"/> Yes <input type="checkbox"/> No	<p>1. <u>Homozygous familial hypercholesterolemia (HoFH);</u></p> <ul style="list-style-type: none"> • Genetic confirmation of two mutant alleles at the LDL Receptor, ApoB, PCSK9, or LDLRAP1 gene locus; OR (ARH adaptor protein gene locus) • An untreated LDL-C > 500mg/dL with either: <ul style="list-style-type: none"> i.) Cutaneous or Tendon Xanthoma before age 10 years <li style="text-align: center;">or ii.) Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (≥ 190 mg/dL);
2) <input type="checkbox"/> Yes <input type="checkbox"/> No	<p>OR</p> <p>2. Severe Primary Hypercholesterolemia, including heterozygous familial hypercholesterolemia [HeFH], at high risk for ASCVD defined a 10-year ASCVD risk percent of ≥ 20% or patients ages 40-75 yrs with diabetes and 10 yr ASCVD risk > 7.5%, LDL 80-189); (https://www.acc.org/ASCVDApp)</p> <p>Diagnosis of HeFH (one of the following)::</p> <ul style="list-style-type: none"> • Functional mutation in the LDLR, apoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene; or • Corneal arcus (seen in ages < 45 yrs), or xanthelasma (seen in ages < 25yrs); or tendon xanthomas; or • Clinical diagnosis based on the World Health Organization Dutch Lipid Clinical Network criteria with a “probable familial hypercholesterolemia” score of ≥ 6 points OR <i>definite</i> diagnosis by Simon Broom criteria;
3) <input type="checkbox"/> Yes <input type="checkbox"/> No	OR
	3. Established Atherosclerotic Cardiovascular Disease (ASCVD);
AND	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Documentation of recent (within the last 30 days) LDL-C of one of the following <u>despite</u> maximally tolerated lipid lowering therapy: <ul style="list-style-type: none"> a. <u>LDL-C:</u> > 70 mg/dl and Very High Risk ASCVD; <li style="text-align: center;">OR b. <u>LDL-C:</u> > 100 mg/dL for severe primary hypercholesterolemia (including HeFH) without ASCVD but with multiple risk factors that increase subsequent risk of ASCVD; <p>LDL-C: _____ Lab date: _____</p>
AND	

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CRITERIA/ADDITIONAL DOCUMENTATION

REPATHA™ (evolocumab)



Yes No 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:
 - Myopathy: unexplained muscle pain or weakness accompanied by CK elevations; **OR**
 - Myalgia: muscle symptoms without CK elevations and meets both of the following:
 - i. Intolerable statin associated muscle symptoms (SAMS) persisting at least two weeks which disappeared with discontinuation of the statin therapy and recurred with a statin re-challenge; **AND**
 - ii. Intolerant despite re-challenge with titration from lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly);

AND

Yes No 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 $\geq 15\%$ LDL-C reduction is required despite adherence with statin therapy, use of Zetia is **not** required;

AND

Yes No Repatha use will be concomitantly with a maximally-tolerated statin and Zetia unless contraindications, intolerance or the use of Zetia is not required;

AND

Yes No Not used in combination with Juxtapid® (lomitapide) or another PCSK9 inhibitor.

Recommended Repatha Dosing Regimen

Diagnosis	Repatha Dosing Regimen
<ul style="list-style-type: none"> • Established Cardiovascular Disease (ASCVD) • Primary Hypercholesterolemia <p style="text-align: center;">OR</p>	140mg SC every 2 weeks
<ul style="list-style-type: none"> • Established Cardiovascular Disease (ASCVD) • Primary Hypercholesterolemia • Homozygous Familial Hypercholesterolemia 	420mg SC once monthly

REAUTHORIZATION CRITERIA: (52 weeks approval duration)

Yes No Prescribed by or in consultation with a cardiologist, endocrinologist or lipid specialist;

AND

Yes No Evidence of adherence (defined as 85% consistent pharmacy claims) to ongoing concomitant lipid lowering therapy as applicable;

AND

Yes No Lab results obtained within the last 12 weeks show an LDL-C reduction since initiation of Repatha therapy;
LDL-C: _____ **Lab Date:** _____

AND

Yes No Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and that they understand that the Mississippi Division of Medicaid may perform a routine audit and request the medical information necessary to verify the accuracy of information provided.

BACKGROUND INFORMATION/ASCVD RISK CALCULATOR CAN BE FOUND IN THE INSTRUCTION SHEET

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