POLICY

A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
1. Repatha is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.
2. Repatha is indicated as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol.
3. Repatha is indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:
1. Current LDL-C level for both initial requests and continuation requests. The level must be dated within the six months preceding the authorization request.
2. Untreated (before any lipid lowering therapy) LDL-C level if requesting Repatha to treat primary hyperlipidemia, heterozygous or homozygous familial hypercholesterolemia.
3. Chart notes confirming clinical atherosclerotic cardiovascular disease (ASCVD) if requesting Repatha to treat clinical ASCVD.

C. CRITERIA FOR APPROVAL

1. Clinical atherosclerotic cardiovascular disease (ASCVD)

Authorization of 6 months may be granted for treatment of clinical atherosclerotic cardiovascular disease when any of the following criteria are met:
   a) Member has a current LDL-C level ≥ 70 mg/dL with clinical ASCVD (See Appendix A) after at least three months of treatment with a high-intensity statin dose. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
b) Member has a current LDL-C level ≥ 70 mg/dL with clinical ASCVD and a contraindication or intolerance to statins (See Appendix B and C).

2. Primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH)
Authorization of 6 months may be granted for treatment of primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH) when both of the following criteria are met:
   a) Member had an untreated (before any lipid lowering therapy) LDL-C level ≥ 190 mg/dL in the absence of a secondary cause.
   b) Member meets one of the following criteria:
      i. Member has current LDL-C level ≥ 100 mg/dL after at least three months of treatment with a high-intensity statin dose. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
      ii. Member has current LDL-C level ≥ 100 mg/dL with a contraindication or intolerance to statins (See Appendix B and C).

3. Homozygous familial hypercholesterolemia (HoFH)
Authorization of 6 months may be granted for treatment of homozygous familial hypercholesterolemia when both of the following criteria are met:
   a) Member had an untreated (before any lipid lowering therapy) LDL-C level ≥ 190 mg/dL in the absence of a secondary cause.
   b) Member meets one of the following criteria:
      i. Member has a current LDL-C level ≥ 100 mg/dL after at least three months of treatment with a high-intensity statin dose. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
      ii. Member has a current LDL-C level ≥ 100 mg/dL with a contraindication or intolerance to statins (See Appendix B and C).
      iii. Member has received Juxtapid or Kynamro.
      iv. Member has been treated regularly with lipid apheresis.

D. APPENDICES
APPENDIX A. Clinical ASCVD
   • Acute coronary syndromes
   • Myocardial infarction
   • Stable or unstable angina
   • Coronary or other arterial revascularization procedure (e.g., percutaneous coronary angioplasty [PTCA], coronary artery bypass graft [CABG] surgery)
   • Stroke of presumed atherosclerotic origin
   • Transient ischemic attack (TIA)
   • Non-cardiac peripheral arterial disease of presumed atherosclerotic origin (e.g., carotid artery stenosis)
   • Obstructive coronary artery disease (defined as fifty percent or greater stenosis on cardiac computed tomography angiogram or catheterization)

APPENDIX B. Statin-associated muscle symptoms (SAMS) and statin re-challenge
   • Intolerable SAMS persisting at least two weeks, which subsided when the medication was discontinued, and reemerged with a statin re-challenge.
NOTE: Re-challenge must be with a different statin.

- Statin-associated elevation in creatine kinase (CK) level ≥ 10 times upper limit of normal (ULN)

NOTE: Statin re-challenge is NOT required for members who have experienced an elevation of CK level ≥10 times ULN after receiving lipid-lowering therapy (LLT) with a statin.

APPENDIX C. Contraindications to statins

- Active liver disease, including unexplained persistent elevations in hepatic transaminase levels (e.g., alanine transaminase (ALT) level ≥ 3 times ULN)
- Women who are pregnant or may become pregnant
- Nursing mothers

D. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members who achieve or maintain an LDL-C reduction (e.g., LDL-C is now at goal, robust lowering of LDL-C).

E. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. ADMINISTRATIVE GUIDELINES

Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

G. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes 432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/CVS’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

H. REFERENCES


**Document History**

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