

ENHANCED SPECIALTY GUIDELINE MANAGEMENT

REPATHA (evolocumab)

POLICY

I. 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

- A. Repatha is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.
- B. 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.
- C. 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.

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

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

III. CRITERIA FOR INITIAL APPROVAL

A. 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:

1. 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 AND ezetimibe. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
2. 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) AND ezetimibe. If member has a contraindication or intolerance to only one of the two classes of drugs, member must have at least three months of treatment with the alternate drug class with a current LDL-C level ≥ 70 mg/dL.

B. 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:

1. Member had an untreated (before any lipid lowering therapy) LDL-C level ≥ 190 mg/dL in the absence of a secondary cause.
2. Member meets one of the following criteria:
 - a. Member has current LDL-C level ≥ 100 mg/dL after at least three months of treatment with a high-intensity statin dose AND ezetimibe. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
 - b. Member has current LDL-C level ≥ 100 mg/dL with a contraindication or intolerance to statins (See Appendix B and C) AND ezetimibe. If member has a contraindication or intolerance to only one of the two classes of drugs, member must have at least three months of treatment with the alternate drug class with a current LDL-C level ≥ 100 mg/dL.

C. 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:

1. Member had an untreated (before any lipid lowering therapy) LDL-C level ≥ 190 mg/dL in the absence of a secondary cause.
2. Member meets one of the following criteria:
 - a. Member has a current LDL-C level ≥ 100 mg/dL after at least three months of treatment with a high-intensity statin dose AND ezetimibe. 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 ≥ 100 mg/dL with a contraindication or intolerance to statins (See Appendix B and C) AND ezetimibe. If member has a contraindication or intolerance to only one of the two classes of drugs, member must have at least three months of treatment with the alternate drug class with a current LDL-C level ≥ 100 mg/dL.
 - c. Member has been treated regularly with lipid apheresis.

IV. 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).

V. APPENDICES

APPENDIX A. Clinical ASCVD^{2,11,12}

- 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^{2,9}

- 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

VI. REFERENCES

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