Effective Date: 9/2017
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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 (LDL-C).
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.
C. If patient has contraindication or intolerance to statins, chart notes confirming the contraindication or Intolerance (See Appendix B and C).

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 history of clinical ASCVD (See Appendix A)
2. 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.
3. 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 LDL-C reduction (e.g., LDL-C is now at goal, robust lowering of LDL-C).

V. QUANTITY LIMITS

Repatha 140mg: 2 syringes per 28 days
Repatha Push 420mg: 1 cartridge per 28 days

VI. 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]

- Score of 7 or higher on the Statin-Associated Muscle Symptom Clinical Index (SAMS-CI)
- 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)
- Pregnancy or planned pregnancy
- Breastfeeding

VI. REFERENCES

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