Effective Date: 9/2017
Reviewed: 12/2018, 9/2019, 6/2020, 3/2021, 3/2023
Scope: Medicaid

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 in adults with established cardiovascular disease to reduce the risk of myocardial infarction, stroke, and coronary revascularization.
B. Repatha is indicated as an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C.
C. Repatha is indicated as an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C.
D. Repatha is indicated as an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of 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. (See Appendix A).
D. If member 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 both of the following criteria are met:

1. Member has a history of clinical ASCVD (See Appendix A).
2. Member meets at least one of the following criteria:
   a. Member has a current LDL-C level ≥ 70 mg/dL after at least three months of treatment with a high-intensity statin dose in combination with 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 ≥ 70 mg/dL with contraindication or intolerance to statins (See Appendix B and C).

B. Primary hyperlipidemia

Authorization of 6 months may be granted for treatment of primary hyperlipidemia 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 at least 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 in combination with 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).

C. Heterozygous familial hypercholesterolemia (HeFH)

Authorization of 6 months may be granted for treatment of heterozygous familial hypercholesterolemia when both of the following criteria are met:

1. Member meets either of the following criteria:
   a. Member is 18 years of age or older and had an untreated (before any lipid lowering therapy) LDL-C level ≥ 190 mg/dL in the absence of a secondary cause.
   b. Member is less than 18 years of age and had an untreated (before any lipid lowering therapy) LDL-C level ≥ 160 mg/dL in the absence of a secondary cause.
2. Member meets at least 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 in combination with 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).

D. 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 meets either of the following criteria:
   a. Member is 18 years of age or older and had an untreated (before any lipid lowering therapy) LDL-C level ≥ 190 mg/dL in the absence of a secondary cause.
   b. Member is less than 18 years of age and had an untreated (before any lipid lowering therapy) LDL-C level ≥ 160 mg/dL in the absence of a secondary cause.
2. Member meets at least 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 in combination with 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).
3. Member's dose does not exceed FDA approved labeling

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who achieve or maintain an LDL-C reduction (e.g., LDL-C is now at goal, robust lowering of LDL-C) and the member's dose does not exceed FDA approved labeling.

V. QUANTITY LIMITS

Repatha 140mg/ml: 2 syringes or pens (2ml) per 28 days [daily dose of 0.08]
Repatha Push 420mg/3.5ml: 1 cartridge (3.5ml) per 28 days [daily dose of 0.13], with post-limit exception of 2 cartridges (7.5ml) per 28 days [daily dose of 0.27] for HoFH if a clinically meaningful response is not achieved in 12 weeks with 420mg once monthly dose or if member is receiving concomitant lipid apheresis

VI. DOSING

Indication	Dosing
Adults with established cardiovascular disease or with primary hyperlipidemia	• Repatha 140 mg every 2 weeks OR 420 mg once monthly administered subcutaneously
Pediatric patients aged 10 years and older with HeFH:	• Repatha 140 mg every 2 weeks OR 420 mg once monthly administered subcutaneously
Adults and pediatric patients aged 10 years and older with HoFH	• Repatha 420 mg once monthly administered subcutaneously ○ 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 their apheresis schedule. Administer Repatha after the apheresis session is complete.

VII. APPENDICES

APPENDIX A. Clinical ASCVD

- Acute coronary syndromes
- Myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization procedure (e.g., percutaneous coronary intervention [PCI], 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, lower extremity PAD)
- Obstructive coronary artery disease (defined as fifty percent or greater stenosis on cardiac computed tomography angiogram or catheterization)
- Coronary Artery Calcium (CAC) Score ≥ 1000

APPENDIX B. Statin-associated muscle symptoms (SAMS) and statin re-challenge

- 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

VIII. REFERENCES

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