

<b>Effective Date: 9/2017</b>
Reviewed: 12/2018, 9/2019, 6/2020, 3/2021, 3/2023, 6/2024
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  $\geq 70$  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.

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- b. Member has a current LDL-C level  $\geq 70$  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  $\geq 190$  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  $\geq 100$  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  $\geq 100$  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  $\geq 190$  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  $\geq 160$  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  $\geq 100$  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  $\geq 100$  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  $\geq 190$  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  $\geq 160$  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  $\geq 100$  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  $\geq 100$  mg/dL with a contraindication or intolerance to statins (See Appendix B and C).
3. Member's dose does not exceed FDA approved labeling

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**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**

<b>Indication</b>	<b>Dosing</b>
Adults with established cardiovascular disease or with primary hyperlipidemia	<ul style="list-style-type: none"> <li>Repatha 140 mg every 2 weeks OR 420 mg once monthly administered subcutaneously</li> </ul>
Pediatric patients aged 10 years and older with HeFH:	<ul style="list-style-type: none"> <li>Repatha 140 mg every 2 weeks OR 420 mg once monthly administered subcutaneously</li> </ul>
Adults and pediatric patients aged 10 years and older with HoFH	<ul style="list-style-type: none"> <li>Repatha 420 mg once monthly administered subcutaneously               <ul style="list-style-type: none"> <li>The dosage can be increased to 420 mg every 2 weeks if a clinically meaningful response is not achieved in 12 weeks.</li> </ul> </li> <li>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.</li> </ul>

**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  $\geq$  1000

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

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- Score of 7 or higher on the Statin-Associated Muscle Symptom Clinical Index (SAMS-CI)
- Statin-associated elevation in creatine kinase (CK) level  $\geq 10$  times upper limit of normal (ULN)  
**NOTE:** Statin re-challenge is NOT required for members who have experienced an elevation of CK level  $\geq 10$  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  $\geq 3$  times ULN)
- Pregnancy or planned pregnancy
- Breastfeeding

## VIII. REFERENCES

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