Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Repatha (evolocumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial authorization – 6 months Continuation of therapy – 12 months

Medications	Quantity Limit
Repatha (evolocumab) 140 mg/ml prefilled syringe or auto-injector*	2 prefilled syringes or auto-injectors per 28 days
Repatha (evolocumab) 420 mg/3.5 ml prefilled cartridge	1 prefilled cartridge per month

*May approve one additional prefilled syringe or auto-injector of Repatha every 28 days for individuals utilizing Repatha 420 mg per month.

APPROVAL CRITERIA

Initial requests for Repatha (evolocumab) may be approved if the following criteria are met:

I. Individual is at high risk for atherosclerotic cardiovascular disease (ASCVD) events as identified by one of the following:
   A. Individual has Homozygous Familial Hypercholesterolemia (HoFH) confirmed by (Cuchel 2014, Singh 2015):
      1. Presence of two mutant alleles at the LDLR, apolipoprotein B (apoB), PCSK9 or ARH adaptor protein (LDLRAP1) gene locus; **OR**
      2. One of the following:
         a. An untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L); **OR**
         b. Treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) **AND** one of the following:
            i. Cutaneous or tendonous xanthoma before age of 10 years; **OR**
            ii. Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than190 mg/dL);

   OR

   B. Individual Heterozygous Familial Hypercholesterolemia (HeFH) confirmed by (Singh 2015, WHO 1999):
      1. Presence of a mutation in LDLR, apolipoprotein B (apoB), or PCSK9, ARH adaptor protein (LDLRAP1) gene; **OR**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

2. World Health Organization (WHO)/Dutch Lipid Network Criteria with score of greater than eight points;

OR

C. Individual has a history of clinical atherosclerotic cardiovascular disease (ASCVD), including **one or more** of the following (AHA/ACC 2018):
   1. Acute coronary syndromes;
   2. Coronary artery disease (CAD);
   3. History of myocardial infarction (MI);
   4. Stable or unstable angina;
   5. Coronary or other arterial revascularization;
   6. Stroke;
   7. Transient ischemic attack (TIA);
   8. Peripheral arterial disease (PAD) ;

AND

II. Individual meets one of the following:
   A. Individual is on a high intensity statin therapy, or statin therapy at the maximum tolerated dose(high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher) (AHA/ACC 2018, AACE 2017); **OR**
   B. Individual is statin intolerant based on one of the following:
      1. Inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, demonstrated by intolerable symptoms or clinically significant biomarker changes (NLA 2014); **OR**
      2. Statin associated rhabdomyolysis after a trial of one statin;

   OR

   C. Individual has a contraindication for statin therapy including active liver disease, unexplained persistent elevation of hepatic transaminases, or pregnancy;

AND

III. Individual is on ezetimibe in addition to statin therapy (only applies to individuals on statin therapy) (ACC 2016);

AND

IV. Individual, excluding HoFH, has achieved suboptimal lipid lowering response, despite at least 90 days of compliant lipid lowering therapy and lifestyle modificationsas defined (AHA/ACC 2018):
   A. For individuals where initial LDL-C is known:
      1. Less than 50% reduction LDL-C; **OR**
   B. For individuals where initial LDL-C is unknown:
      1. ASCVD and LDL-C remains greater than

Market Applicability							
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Applicable	X	X	X	X	X	X	NA

or equal to 70mg/dL; **OR**

2. No history of ASCVD and LDL-C remains greater than or equal to 100mg/dL.

Continuation requests for Repatha (evolocumab) may be approved when the following criteria are met:

I. Individual continues to receive concomitant maximally tolerated statin therapy (unless contraindication or individual is statin intolerant); **AND**
II. Confirmation of LDL reduction has been provided.

Repatha (evolocumab) may not be approved for the following:

I. All other indications not included above; **OR**
II. Concurrent use Juxtapid (lomitapide) or Kynamro (mipomersen).

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

1. Cuchel M, Bruckert E, Ginsberg HN, et. al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. *European Heart Journal.* 2014; 35: 2146–2157.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 11, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Grundy SM, Stone NJ, Bailey AL, et. al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol. *J Am Coll Cardiol.* 2018. https://doi.org/10.1016/j.jacc.2018.11.003.
5. Guyton JR, Bays HE, Grundy SM, Jacobson TA. The National Lipid Association Statin Intolerance Panel. An assessment by the Statin Intolerance Panel: 2014 update. *J Clin Lipidol*. 2014;8(3 Suppl):S72–81.
6. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for management of dyslipidemia and prevention of cardiovascular disease. *Endocr Pract*. 2017;23(Suppl 2):1-87.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

8. Singh S, Bittner V. Familial hypercholesterolemia--epidemiology, diagnosis, and screening. *Curr Atheroscler Rep*. 2015; 17(2):482.
9. World Health Organization. Familial hypercholesterolemia—report of a second WHO Consultation. Geneva, Switzerland: World Health Organization, 1999. Available at: http://whqlibdoc.who.int/hq/1999/WHO_HGN_FH_CONS_99.2.pdf?ua=1. Accessed: July 11, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
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