Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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Repatha (evolocumab)

DRUG.00078

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial authorization – 3 months Continuation of therapy – 12 months

Medications	Quantity Limit
Repatha (evolocumab)	2 prefilled syringes or auto-injectors per 28 days 1 Pushtronex 420 Mg/3.5 Ml Subcutaneous Wearable Injector per month Individuals with Homozygous Familial Hypercholesterolemia (HoFH) may receive one additional prefilled syringe or auto-injector every 28 days. For individuals without HoFH, requests for a greater quantity will be reviewed on a case by case basis.

APPROVAL CRITERIA

Requests for **initiation therapy of** Repatha (evolocumab) may be approved if the following criteria are met:

I. Individual is at high risk for Acute Coronary Syndrome (ACS) as identified by:
   A. Homozygous Familial Hypercholesterolemia (HoFH), in individuals age 13 years and older, confirmed by one or more of the following:
      1. Presence of two mutant alleles at the LDLR, apoB, PCSK9 or ARH adaptor gene locus; **OR**
      2. An untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L) or 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);

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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OR

B. Heterozygous Familial Hypercholesterolemia (HeFH), in individuals age 18 years and older, confirmed by one or more of the following:
   1. Presence of a mutation in LDLR, ApoB, or PCSK9, ARH adaptor protein (LDLRAP1) gene; **OR**
   2. WHO/Dutch Lipid Network Criteria with score of greater than eight points;

OR

C. History of Clinical Atherosclerotic Cardiovascular Disease (ASCVD), including at one or more of the following:
   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. 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, where high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher; **OR**
   B. Individual is statin intolerant, as defined by the National Lipid Association Statin Intolerance Panel and includes all of the following:
      1. Inability to tolerate at least two statins, with at least one started at the lowest starting daily dose; **AND**
      2. Statin dose reduction is attempted for symptom and biomarker abnormality resolution, rather than discontinuation of statin therapy altogether; **AND**
      3. Intolerable symptoms or abnormal biomarker changes are reversible upon statin discontinuation, but reproducible by re-challenge of statins, if clinically appropriate. Statin re-challenge may be appropriate for individuals with all of the following:
         i. Symptomatic; **AND**
         ii. Creatine kinase is less than four times the upper limit of normal per laboratory reference range; **AND**
         iii. AST/ALT are less than three times upper limit of normal, per laboratory reference ranges;

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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AND

4. Symptoms or biomarker abnormalities are not attributable to established predispositions or conditions recognized to increase the risk of statin intolerance, such as:
    i. Hypothyroidism;
    ii. Drug interactions;
    iii. Concurrent illness;
    iv. Significant changes in physical activity/exercise;
    v. Underlying muscle disease;

OR

C. Individual has a condition that is a contraindication for statin therapy including active liver disease, unexplained persistent elevation of serum transaminases, or pregnancy, which does not exist for Repatha;

AND

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

AND

IV. High risk individual, excluding HoFH, has achieved suboptimal lipid lowering response, despite at least 90 days of compliant lipid lowering therapy and lifestyle modifications, where suboptimal response is defined:
    A. For individuals where initial LDL-C is known:
        1. Less than 50% reduction LDL-C;
    B. For individuals where initial LDL-C is unknown:
        1. There is confirmation that CVD and LDL-C remains greater than or equal to 70mg/dl; **OR**
        2. No documented history of CVD and LDL-C remains greater than or equal to 100mg/dl;

Requests for **continuation of therapy** of Repatha (evolocumab) may be approved if the following criteria are met:

I. Criteria listed above have been met; **AND**
II. There is confirmation of LDL reduction.

Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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Repatha (evolocumab) may **not** be approved when used concurrently with 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

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Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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