Blue Cross and Blue Shield of Vermont and The Vermont Health Plan
Prior Approval Guidelines

REPATHA™ (evolocumab)

DESCRIPTION: Evolocumab is a human monoclonal immunoglobulin G2 (IgG2) directed against human proprotein convertase subtilisin kexin 9 (PCSK9).

Evolocumab is a human monoclonal IgG2 directed against human proprotein convertase subtilisin kexin 9 (PCSK9). Evolocumab binds to PCSK9 and inhibits circulating PCSK9 from binding to the low density lipoprotein (LDL) receptor (LDLR), preventing PCSK9-mediated LDLR degradation and permitting LDLR to recycle back to the liver cell surface. By inhibiting the binding of PCSK9 to LDLR, evolocumab increases the number of LDLRs available to clear LDL from the blood, thereby lowering LDL-C levels.

INDICATION(S): REPATHA™ is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C).

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.

The recommended subcutaneous dosage of REPATHA in patients with HeFH or patients with primary hyperlipidemia with established clinical atherosclerotic CVD is either 140 mg every 2 weeks OR 420 mg once monthly. The recommended subcutaneous dosage of REPATHA in patients with HoFH is 420 mg once monthly. In patients with HoFH, measure LDL-C levels 4 to 8 weeks after starting REPATHA, since response to therapy will depend on the degree of LDL-receptor function.

REASONS FOR PA:
☑ Cost  ☑ Potential for misuse  ☑ Toxicity

CRITERIA for APPROVAL:
1. Patient has a diagnosis of homozygous familial hypercholesterolemia. OR
2. Patient has a diagnosis of heterozygous familial hypercholesterolemia AND has tried for 60 days and failed to reach LDL-c goals using ONE high intensity statin (atorvastatin 80 mg/Crestor 20 mg) OR
3. Patient has tried for 60 days and failed to reach LDL-c goals using TWO high intensity statins (Atorvastatin 80 mg/ Crestor 20 mg) when used as secondary prevention for ASCVD or primary prevention for diabetes OR
4. Experienced clinically significant adverse effects (e.g., increase in ALTs of 3x ULN; myopathy) while on at least TWO trials of high intensity statins when used as secondary prevention for ASCVD or primary prevention for diabetes AND
5. Is prescribed by a Cardiologist or in consultation with a Cardiologist AND
6. Patient has been initiated on a low-fat diet, which supplies <20% of energy from fat for at least two months AND
7. Patient is at least 18 years of age.
8. Dosing 140mg once every 2 week/ OR 420mg once monthly SQ for HeFH.
9. Dosing 420mg once monthly SQ for HoFH

REASONS for DENIAL of BENEFIT:
1. Patient is hypersensitive to Praluent or any component of its formulation.
2. Patient does not meet above criteria.

BENEFIT: RENEWAL CRITERIA:
1. Praluent is prescribed by or in consultation with a cardiologist.
2. Patient has demonstrated LDL reduction to goal.

BENEFIT APPROVAL:
Initial approval for a period of 6 months. Renewal approval period: 24 months. Members may only obtain a 30 days supply at a time

References: REPATHA™ (evolocumab) Prescribing Information Amgen Inc.Thousand Oaks, CA 91320-1799 08/2015 v1