PRALUENT (alirocumab) is proprotein convertase subtilisin Kexin type 9 (PCSK9) enzyme involved in the regulation of cholesterol levels by modulating low-density lipoprotein cholesterol receptors. Praluent is a human monoclonal antibody that binds to PCSK9 helps regulate the amount of cholesterol in the bloodstream. Rare gain of function mutations in PCSK9 lead to a high LDL-C level and premature coronary heart diseases. PCSK9 levels are also increased with statin therapy through negative feedback, which promotes LDL-receptor degradation and decreases the efficacy of LDL-C lowering with statins. In phase I, II and III trials inhibition of PCSK9 with monoclonal antibodies has produced additional 50-60% decrease in the LDL-C level when used in combination with statin therapy. Studies have suggested that people with reduced cholesterol levels caused by PCSK9 mutations have a significantly lower than average risk of developing heart disease.

INDICATION (S):
PRALUENT :PCSK9 inhibitor indicated for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease requiring additional lowering of LDL-c in adjunct to diet and maximally tolerated statin therapy. The most common adverse reactions are nasopharyngitis, injection site reactions and influenza. Monitor LDL-c levels within 4 to 8 weeks of initiating or titrating Praluent to assess the patient’s response to the therapy.

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

CRITERIA for APPROVAL:
1. 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
2. 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
3. Experienced clinically significant adverse effects (e.g., increase in LFTs 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
4. Is prescribed by a Cardiologist or in consultation with a Cardiologist AND
5. Patient has been initiated on a low-fat diet, which supplies <20% of energy from fat for at least two months AND
6. Patient is at least 18 years of age.
7. Starting dose for patient is 75 mg once every 2 weeks subcutaneously.

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 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

POLICY HISTORY:
Created 8/2015. Revised 1/16. Corrected Form Fax# 1/17

References: