Pharmacy Benefit Determination Policy

Policy Subject:	PCSK9	**Dates:**	
Policy Number:	SHS PBD52	**Effective Date:**	August 26, 2015
Classification:	Lipid drugs	**Revision Date:**	September 17, 2018
Policy Type:	☐ **Medical** ☒ **Pharmacy**	**Approval Date:**	October 24, 2018
Department:	Pharmacy	**Next Review Date:**	October 2019

Product (check all that apply):	**Clinical Approval By:**
☒ Group HMO/POS	**Medical Directors**
☒ Individual HMO/POS	PHP: Peter Graham, MD
☒ PPO	**Pharmacy and Therapeutics Committee**
☒ ASO	PHP: Peter Graham, MD

Policy Statement:

Physicians Health Plan, PHP Insurance & Service Company, and Sparrow PHP will cover PCSK9 inhibitors through the Pharmacy Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines

Applicable Coding:

Clinical Determination Guidelines:

Document the following with chart notes:

A. Diagnosis and severity
   1. Prescriber: Cardiologist, Endocrinologist or Lipid specialist
   2. Homozygous Familial Hypercholesterolemia (HoFH): 1 below
      a. Genetic Testing: Confirmed presence of the LDLR, APOB, PCSK9 or LDLRAP1 gene
      b. Untreated with LDL >500mg/dL or treated LDL-C > 300mg/dL: 1 below
         - Cutaneous or tendon xanthoma at <10 years old.
         - Increased LDL-C consistent with HoFH in both parents.
   3. Heterozygous Familial Hypercholesterolemia (HeFH): 1 below
      a. Dutch Lipid Clinical Network criteria: Definite diagnosis defined by total score > 8
      b. Simon Broome diagnostic criteria:
         - Adult: Total cholesterol > 290mg/dL or LDL-C > 190mg/dL
         - Child (<16 years old.): Total Cholesterol > 260mg/dL or LDL-C >155mg/d
   4. Clinical Atherosclerotic Cardiovascular Disease (ASCVD):
      a. History of ASCVD or CV event: Acute Coronary Syndromes, myocardial infarction, angina, coronary or other arterial revascularization procedure, stroke, transient ischemic attack, peripheral arterial disease.

B. Other therapies
   1. Non-pharmacological: Lifestyle modifications (e.g. diet, alcohol use, smoking, exercise) attestation from practitioner.
   2. Pharmacological: Statin therapy (one below)
      a. Contraindication: Chronic active liver disease diagnosis for > 3 months and/or unexplained persistent increased serum transaminases.
      b. Failed high intensity statins and combination therapy (3-month trial): All below
         - Atorvastatin (40mg/day to 80mg/day) and (rosuvastatin 20mg/day to 40mg/day)
         - High intensity statin with additional lipid lowering agent such as fibrate or ezetimibe.
         - LDL-C (within last month): ≥ 100mg/dL with ASCVD or ≥130mg/dL without ASCVD
      c. Significant adverse effect (2 weeks): Both below
         - Muscle symptoms: Myalgia, myositis or rhabdomyolysis.
         - High intensity statin dosage reduction or statin re-challenge with low intensity statin and reappearance of muscle symptoms.

C. Dosage regimen
   1. Praluent (alirocumab SC): 75mg q 2 weeks or 300mg q 4 weeks; max 150mg q 2 weeks.
   2. Repatha (evolocumab SC): 140 q 2 weeks or 420 q month; HoFH - max. dose 420mg q 2 weeks

D. Approval
   1. Initial: 6 months.
   2. Re-approval: 1 year (1 below)
      - Absolute reduction LDL-C: ≥ 40mg/dL
      - Reduction below LDL-C ≤ 100mg/dL with ASCVD or ≤130mg/dL without ASCVD

E. Exclusions:
   1. Pregnant/breast-feeding
   2. Women of childbearing potential: Not using effective contraceptive methods for the duration of PCSK9 inhibitor therapy
   3. Triglycerides > 400 mg/dL

Appendix I: Monitoring & Patient Safety

Drug	Adverse Reaction	Monitoring Parameters	REMS
Praluent	• Local: Injection site Rxs (7-17%) • Preg.: Adverse events not observed in animal studies;	• Lab: LDL-C within 4-8 wks of start or dose titration. • Misc.: Hypersensitivity rx.	N/A
Repatha	• Resp.: Nasopharyngitis (6-11%), URI (9%) • Preg.: Adverse events not observed in animal studies	• Lab: LDL-C within 4-8 wks of start; Lipid profile (HeFH) • Misc.: Hypersensitivity rx.	N/A

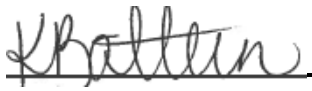
References and Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Repatha & Praluent accessed Sept. 2018.
2. Efficacy and safety of alirocumab in reducing lipids and cardiovascular events. *NEJM* 2015;372(16):1489-99.
3. Efficacy and safety of evolocumab in reducing lipids and cardiovascular events. *NEJM* 2015;372(16)1500-9.
4. American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for the management of dyslipidemia and prevention of cardiovascular disease. Endocr Pract 2017; 23:1-87.
5. Focused Update of the 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease

Approved By:

10/24/18

Peter Graham, MD – PHP Executive Medical Director — Date



10/24/18

Human Resources – Kurt Batteen — Date