MEDICATION POLICY

Generic Name: PCSK9 Inhibitors

Therapeutic Class or Brand Name: PCSK9 Inhibitors

Applicable Drugs (if Therapeutic Class)**:**

Praluent® (alirocumab), Repatha™ (evolocumab)

Date of Origin: 8/19/15 **Date Last Reviewed/Revised:** 8/29/16

GPI Code: 3935001000, 3935002000

Prior Authorization Criteria (may be considered medically necessary when criteria I through IV are met):

I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:
   A. Heterozygous familial hypercholesterolemia (HeFH) and criterion 1 is met:
      1. Minimum age requirement: 18 years old.
   B. Homozygous familial hypercholesterolemia (HoFH) and criterion 1 is met:
      1. Minimum age requirement: 13 years old.
   C. Clinical atherosclerotic cardiovascular disease (CVD) and criterion 1 is met:
      1. Minimum age requirement: 18 years old.

II. Documentation that patient meets ONE of the following criteria A or B:
   A. Patient is taking, will continue to take, and is adherent to high-intensity statin therapy (atorvastatin 40mg to 80 mg per day or rosuvastatin 20mg to 40mg per day) at the maximally tolerated dose.
   B. Documentation that patient meets criteria 1 AND 2 below:
      1. Patient is intolerant to BOTH options for high-intensity statin therapy (atorvastatin 40mg per day and rosuvastatin 20mg per day).
      2. Patient is taking, will continue to take, and is adherent to low- or moderate-intensity statin therapy at the maximally tolerated dose.

III. Documentation that current fasting LDL-C is at least 100mg/dL (measured within the previous 30 days).

IV. Prescriber must be a doctor of internal medicine, cardiologist, or endocrinologist.

Exclusion Criteria:

- Concurrent use of a PCSK9 Inhibitor with another PCSK9 Inhibitor, Juxtapid® (lomitapide), or Kynamro® (mipomersen).

Other Criteria:

- In order for the patient to be considered as being adherent, the proportion of days covered must be at least 75% for the previous 6 months as evidenced by pharmacy claims review.

Quantity/Days Supply Restrictions:

- Repatha™:
  - Clinical atherosclerotic CVD, HeFH: 2 pens or syringes per 28 days.
  - HoFH: 1 Pushtronex™ system per 28 days.
- Praluent®: 2 pens or syringes per 28 days.

Approval Length:

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective. Documentation of ONE of the following a or b is also required:
  a. Decrease of fasting LDL-C of at least 45% from baseline since starting therapy with the PCSK9 inhibitor.
  b. Current fasting LDL-C is at least 100mg/dL (measured within the previous 30 days).

Appendix:

N/A

References:

1. http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a.
2. http://products.sanofi.us/praluent/praluent.pdf.
3. http://pi.amgen.com/united_states/repatha/repatha_pi_hcp_english.pdf.
4. Medi-Span.

5. https://www.bluecrossmn.com/healthy/public/portalcomponents/PublicContentServlet?contentId=P11GA_13569744.
6. https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Ox_MPUB_Future_Pharmacy/Med_Nec_Praluent.PDF.
7. http://www.bcbsnc.com/assets/services/public/pdfs/formulary/PCSK9_criteria.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
8/29/2016	1. **Changed** "HoFH: 3 pens or syringes per 28 days" **to** "HoFH: 1 Pushtronex™ system per 28 days" below "Repatha™:" **under Quantity/Days Supply Restrictions**. 2. **Updated** "http://notes.bluecrossmn.com/web/medpolman.nsf/52a80a84dabdaf9586257ae2007b7940/1074a62f0f3d366286257e6f00583240/$FILE/MN_PS_PCSK9_PA_ProgSum_0515.pdf" **to** "https://www.bluecrossmn.com/healthy/public/portalcomponents/PublicContentServlet?contentId=P11GA_13569744" **under References**.
12/18/2015	1. **Changed** "Documentation that current LDL-C is at least 100mg/dL (measured within the previous 30 days)" **to** "Documentation that current fasting LDL-C is at least 100mg/dL (measured within the previous 30 days)" **under Prior Authorization Criteria**. 2. **Changed** "IV. Prescriber must be a cardiologist, endocrinologist, or lipid specialist" **to** "IV. Prescriber must be a doctor of internal medicine, cardiologist, or endocrinologist" **under Prior Authorization Criteria**. 3. **Changed** "a. Decrease of LDL-C of at least 45% from baseline since starting therapy with the PCSK9 inhibitor; b. Current LDL-C is at least 100mg/dL (measured within the previous 30 days)" **to** "a. Decrease of fasting LDL-C of at least 45% from baseline since starting therapy with the PCSK9 inhibitor; b. Current fasting LDL-C is at least 100mg/dL (measured within the previous 30 days)" **following Re-Authorization under Approval Length**.
12/16/2015	1. **Added** "IV. Prescriber must be a cardiologist, endocrinologist, or lipid specialist" **under Prior Authorization Criter**ia.
10/23/2015	1. **Added** "Repatha™ (evolocumab)" **to Applicable Drugs**. 2. **Added** "3935002000" **to GPI Code**. 3. **Changed** "Documented diagnosis of one of the following conditions A or B: A. Heterozygous familial hypercholesterolemia; B. Atherosclerotic cardiovascular disease; Minimum age requirement: 18 years old" **to** "Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis: A. Heterozygous familial hypercholesterolemia (HeFH) and criterion 1 is met: 1. Minimum age requirement: 18 years old; B. Homozygous familial hypercholesterolemia (HoFH) and criterion 1 is met: 1. Minimum age requirement: 13 years old; C. Clinical atherosclerotic cardiovascular disease (CVD) and criterion 1 is met: 1. Minimum age requirement: 18 years old" **under Prior Authorization Criteria**. 4. **Changed** "2 pens or syringes per 28 days" **to** "Repatha™: Clinical atherosclerotic CVD, HeFH: 2 pens or syringes per 28 days; HoFH: 3 pens or syringes per 28 days; Praluent®: 2 pens or syringes per 28 days" **under Quantity/Days Supply Restrictions**. 5. **Added** "http://pi.amgen.com/united_states/repatha/repatha_pi_hcp_english.pdf" **to References**. 6. **Updated** "https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Ox_MPUB_Future_Pharmacy/Med_Nec_Praluent.pdf" **to** "https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Ox_MPUB_Future_Pharmacy/Med_Nec_Praluent.PDF" **under References**.