Generic Name: PCSK9 Inhibitors

Therapeutic Class or Brand Name: PCSK9 Inhibitors

Applicable Drugs (if Therapeutic Class): Praluent® (alirocumab), Repatha™ (evolocumab)

Preferred: Praluent® (alirocumab),

Non-preferred: Repatha™ (evolocumab)

Date of Origin: 8/19/2015

Date Last Reviewed / Revised: 8/24/2021

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through II 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 following criterion and conditions are met:

      1. Diagnosed with genetic typing OR measured LDL-C ≥ 190 mg/dL prior to treatment with a statin:

      2. Minimum age requirement: 18 years old.

   B. Homozygous familial hypercholesterolemia (HoFH) and criterion is met:

      1. Minimum age requirement: 13 years old.

   C. Clinical atherosclerotic cardiovascular disease (ASCVD)and criterion 1 is met:

      1. Minimum age requirement: 18 years old.

II. Documentation that patient meets the following criteria A and B:

   A. Treatment with maximally tolerated statin (e.g. atorvastatin 40mg to 80 mg per day or rosuvastatin 20mg to 40mg per day) and ezetimibe daily for ≥12 weeks and LDL-C remains ≥70 mg/dL or a 50% reduction in LDL-c has not been achieved.

   B. Patient will continue to take and is adherent to high-intensity statin therapy (e.g atorvastatin 40mg to 80 mg per day or rosuvastatin 20mg to 40mg per day) at the maximally tolerated dose.

Exclusion Criteria

- Concurrent use with another PCSK9 Inhibitor.

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

Quantity / Days Supply Restrictions

- Repatha:
  - Clinical atherosclerotic CVD, HeFH: 2 pens/syringes or 1 Pushtronex system per 28 days.
  - HoFH: 1 Pushtronex system per 28 days.
- Praluent:
  - 75 mg/mL or 150 mg/mL: 2 pens/syringes per 28 days.

Approval Length

- **Authorization:** 12 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:
  - Decrease of fasting LDL-C of at least 45% from baseline since starting therapy with the PCSK9 inhibitor.
  - Current fasting LDL-C is ≤ 70 mg/dL (measured within the previous 30 days).

Appendix

N/A

References

1. Stone N., Robinson J., Lichtenstein A., et. al. "2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines." *Circulation* vol. 129,25 Suppl 2 (2014): S1-45. doi:10.1161/01.cir.0000437738.63853.7a. Available at https://www.ahajournals.org/doi/full/10.1161/01.cir.0000437738.63853.7a. Accessed August 24, 2021.

2. Praluent (alirocumab) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals Inc; April 2021. Available at https://www.regeneron.com/downloads/praluent_pi.pdf. Accessed August 24, 2021.
3. Repatha (evolocumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; February 2021. Available at http://pi.amgen.com/united_states/repatha/repatha_pi_hcp_english.pdf. Accessed August 24, 2021.
4. Medi-Span.