AllCare CCO - Prior Authorization Criteria Summary:

Criteria number: 069.2

Criteria title: Approval criteria for PCSK-9 inhibitors

Date of origin: 06/25/2015

Classification: Class Specific

Date of Last Review: 06/18/2026

Drug Class: PCSK9 inhibitors

Date of Next Review: 06/17/2028

References:

- Oregon Health Authority, Department of Medical Assistance, OAR 410-120-0250 (3)
- Oregon Medicaid Pharmaceutical Services Prior Authorization Criteria
- Praluent Package insert: July 2015, Sanofi.
- Jacobson, T., Ito, M., Maki, K., et al. National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia: Part 1—Full Report. Journal of Clinical Lipidology. March–April, 2015Volume 9, Issue 2, Pages 129–169.
- Stone NJ, Robinson JG, Lichtenstein AH, 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 2014;129:S1-45
- LerocholTM (lerodalcibep-liga) injection [package labeling]. Cincinnati, OH. LIB Therapeutics, Inc.; Dec 2025
- Uptodate: PCSK9 inhibitors: Pharmacology, adverse effects, and use. UpToDate [database online]. Waltham, MA. Updated May 19, 20265. Available at: http://www.uptodate.com/home/index.html. Accessed on 05/28/26.
- Blumenthal RS, et al. 2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2026 Apr 28;153(17):e1154-e1276. doi: 10.1161/CIR.0000000000001423. Epub 2026 Mar 13. PMID: 41824552.

FDA approved indication:

Purpose: To define the process and coverage for Proprotein Convertase Subtilisin/Kexin type 9 (PCSK9) inhibitors for members with familial hypercholesteremia or hyperlipidemia.

Policy: Cover formulary PCSK9 for members who have documented statin intolerance or elevated lipid levels despite optimal treatments with high intensity statins. Members should be high/very high risk of ASCVD based on National Lipid Association guidelines

Agents included in criteria:

alirocumab (Praluent)	preferred, formulary
evolocumab (Repatha)	preferred, formulary
lerodalcibep-liga (Lerochol)	non-preferred, formulary

Approval length: Up to 1 year

Approval criteria for PCSK9 inhibitors:	**Met**	**Not Met**
Criteria #1: Does the member have a diagnosis consistent with FDA approved labelling	Preferred agent: Go to #2 non-preferred agent,	Deny
Criteria #2: Is the member high risk or very high risk of ASCVD (refer to table below) and not at therapeutic goal	Go to #3	Deny
Criteria #3: Are there lab values documenting lipid levels, LFTs	Go to #4	Deny
Criteria #4: Has the member failed or have a contraindication to high intensity statins	Go to #5	Deny
Criteria #5: Is the prescriber a cardiologist or endocrinologist	Preferred agent: Approve x1 year Non-preferred: go to #6	Deny
Criteria #6: For non-preferred agent, has member been unable to achieve clinical goals despite adequate trial with a preferred agent	Approve x1 year	Deny

Reviewed and approved by: AllCare CCO P&T Committee

Date: 07/23/2015