Generic Name: Hypercholesterolemia Agents

Applicable Drugs: Evkeeza (evinacumab-dgnb), Juxtapid® (lomitapide), Nexletol® (bempedoic acid), Nexlizet™ (bempedoic acid and ezetimibe), Praluent® (alirocumab), Repatha™ (evolocumab)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 4/27/2023

Date Last Reviewed / Revised: 1/7/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. The patient meets specific diagnosis criteria listed for the requested medication in Table 1.

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

A. Treatment with two high intensity statins at maximally tolerated dosage (e.g. atorvastatin 40mg to 80 mg per day, 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.

III. Must be prescribed by or in consultation with a doctor of internal medicine, cardiologist, or endocrinologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Repatha and Praluent: Concurrent use of more than one PCSK9 Inhibitor
- Nexlizet: Concurrent use with simvastatin > 20mg, pravastatin > 40mg, or fibrates (other than fenofibrate), documented hypersensitivity reaction to ezetimibe, history of gout or hyperuricemia, history of tendon rupture or tendon disorders, or history of chronic liver disease or abnormal liver enzymes
- Nexletol: Concurrent use with simvastatin > 20mg or pravastatin > 40mg, documented history of tendon rupture or tendon disorders, or history of chronic liver disease or abnormal liver enzymes

OTHER CRITERIA

- For the patient to be considered as being adherent, the proportion of days covered must be at least 75% for the previous 6 months
- Table 1 Medication Specific Criteria for Hypercholesterolemia Agents

Medication	Medication Specific Criteria	Dosing Limits
Injectable Agents		
Praluent® (alirocumab)	○ Clinical ASCVD, HeFH Diagnosed with genetic typing OR measured LDL-C ≥ 190 mg/dL prior to treatment with a statin, or HoFH ○ ≥ 18 years for clinical ASCVD and HoFH, ≥ 8 years for HeFH	75 mg/mL or 150 mg/mL: 2 pens/syringes per 28 days
Repatha™ (evolocumab)	○ Clinical ASCVD, HeFH Diagnosed with genetic typing OR measured LDL-C ≥ 190 mg/dL prior to treatment with a statin, HoFH ○ ≥18 years for clinical ASCVD, ≥10 years for HoFH and HeFH	2 pens/syringes or 1 Pushtronex system per 28 days
Oral Agents		
Juxtapid® (lomitapide)	○ HoFH ○ ≥ 18 years ○ Baseline ALT, AST, alkaline phosphatase, and total bilirubin ○ Pre-treatment LDL-C greater than 400 mg/dL ○ Clinically significant treatment failure or contraindication to Repatha and Praluent. ○ Not used in combination with a PCSK9	60mg once daily (30 capsules per 30 days)
Nexletol® (bempedoic acid),	○ Clinical ASCVD or high risk for ASCVD, HeFH Diagnosed with genetic typing OR measured LDL-C ≥ 190 mg/dL prior to treatment with a statin ○ ≥ 18 years	up to 30 tablets for 30 days.

Nexlizet™ (bempedoic acid and ezetimibe)	○ Clinical ASCVD or high risk for ASCVD, HeFH Diagnosed with genetic typing OR measured LDL-C ≥ 190 mg/dL prior to treatment with a statin ≥ 18 years	Bottle of 180/10 mg tablets (#30) for 30 days.
HoFH: Homozygous familial hypercholesterolemia. HeFH: Heterozygous familial hypercholesterolemia. ASCVD: Clinical atherosclerotic cardiovascular disease. LDL-C: Low-density lipoprotein) cholesterol. ALT: Alanine transaminase. AST: aspartate aminotransferase		

Quantity / Days Supply Restrictions

- Requested quantities not exceeding dosing limits listed in Table 1.

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. Praluent. Prescribing information. Regeneron Pharmaceuticals Inc; 2024. Accessed October 15, 2024. https://www.regeneron.com/downloads/praluent_pi.pdf
2. Repatha. Prescribing information. Amgen Inc; 2021. Accessed October 15, 2024. https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/repatha/repatha_pi_hcp_english.pdf
3. Juxtapid. Prescribing information. Amryt Pharmaceuticals DAC. 2020. Accessed October 15, 2024. https://juxtapid.com/wp-content/uploads/2021/01/prescribing-information.pdf
4. Nexletol. Prescribing information. Esperion Therapeutics Inc. 2024. Accessed October 15, 2024. https://pi.esperion.com/nexletol/nexletol-pi.pdf.

5. Nexlizet. Prescribing information. Esperion Therapeutics Inc; 2024. Accessed October 15, 2024. https://pi.esperion.com/nexlizet/nexlizet-pi.pdf
6. Goldberg AC, Leiter LA, Stroes ESG, et al. Effect of Bempedoic Acid vs Placebo Added to Maximally Tolerated Statins on Low-Density Lipoprotein Cholesterol in Patients at High Risk for Cardiovascular Disease: The CLEAR Wisdom Randomized Clinical Trial [published correction appears in JAMA. 2020 Jan 21;323(3):282]. *JAMA*. 2019;322(18):1780-1788. Accessed October 15, 2024. https://pubmed.ncbi.nlm.nih.gov/31714986/
7. Arnett, Donna K et al. "2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines." *Circulation* vol. 140,11 (2019): e596-e646. Accessed October 15, 2024. https://pubmed.ncbi.nlm.nih.gov/30879355/