Lerodalcibep-liga (LEROCHOL) Injection for Hypercholesterolemia
Criteria for Use
May 2026

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for lerodalcibep.

- ☐ End-stage renal disease on dialysis
- ☐ Advanced heart failure with limited prognosis
- ☐ Severe comorbid non-cardiovascular condition that is expected to limit life expectancy
- ☐ Pregnant or lactating

Inclusion Criteria

One of the following must be selected to meet criteria.

- ☐ History of ASCVD ^1
- ☐ Severe hypercholesterolemia (e.g., HeFH^2, LDL-C^3 $\geq$ 190 mg/dL) without ASCVD

^1 ASCVD=Atherosclerotic cardiovascular disease

^2 HeFH=Heterozygous familial hypercholesterolemia

^3 LDL-C=Low density lipoprotein cholesterol

Additional Inclusion Criteria

All of the following criteria must be selected to meet criteria.

Contraindication, intolerance to or insufficient LDL-C reduction and needs further LDL-C lowering to reduce ASCVD risk consistent with established guidelines after a trial of:

- ☐ Maximally tolerated dose of statin ^4
- ☐ Ezetimibe ^5
- ☐ Monoclonal antibody inhibitor of PCSK9 ^6
- ☐ Inclisiran^7

^4 Maximally tolerated dose of statin may be none. Confirmed statin intolerance is intolerance to at least 2 statins, one at the lowest approved daily dose and trial of alternate day dosing.

^5 Use of a PCSK9 inhibitor with proven cardiovascular benefit (e.g., alirocumab or evolocumab) can be used in patients with elevated lipoprotein a (Lip[a]) who have not met their LDL-C goals with maximally tolerated dose of statin, without requiring use of ezetimibe.

^6 Monoclonal antibody inhibitor of Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitor (mAb PCSK9i, e.g., alirocumab or evolocumab)

^7 There is no evidence to support combining mAb PCSK9i (e.g., alirocumab or evolocumab), inclisiran or lerodalcibep and therefore, should not be done. If LDL-C reduction is inadequate with one of these agents, replacement of the agent is the intent.

Additional Inclusion Criteria – Select if Applicable

- ☐ For females who are pregnant or plan to become pregnant: Lerodalcibep should not be started or should be discontinued when pregnancy is recognized. Treatment of hypercholesterolemia is generally not needed during pregnancy.

☐ For females lactating / breastfeeding or planning to do so: Lack of data on the effect of lerodalcibep on milk production or on the infant. Risks and benefits of lerodalcibep on the mother's need and potential side effects on the infant are considered.

Supplemental Information

- Clinical trials support a reduction in adverse cardiovascular (CV) events (e.g., CV death, myocardial infarction, stroke, etc.) with alirocumab and evolocumab when added to background statin therapy. However, the effect of inclisiran or lerodalcibep on CV morbidity or mortality has not been established.
- Inclisiran is prioritized in the criteria over lerodalcibep because of its longer-term availability (FDA approved December 2021) and at least one of the three ongoing clinical outcome trials is nearing completion. Although it is anticipated that clinical outcome trials will be conducted with lerodalcibep, trial design and details have not been published to date.
    - ORION 4: secondary prevention trial, potential for results in 2026
    - VICTORION-1 PREVENT: primary prevention trial; expected after 2027
    - VICTORION-2 PREVENT: secondary prevention trial; expected completion date is 2027

Refer to the following link for guidance on managing statin intolerance: National Academic Detailing Services - 10-1695_Dyslipidemia_Provider_StatinIntolerance_P97132 - GroupbyCampaign (sharepoint.com)

Revised: N/A
Original: May 2026

Contact: Catherine Kelley, PharmD, National Program Manager, VA Pharmacy Benefits Management Services – Formulary Management (12PBM)