CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Lerochol (lerodalcibep-liga)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Lerochol, approved by the FDA in 2025, is a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor indicated as an adjunct to diet and exercise: to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH). It is a recombinant fusion protein that binds PCSK9.
PCSK9 binds to LDL receptors in the liver to promote their degradation. Inhibiting PCSK9 from binding the LDL receptors increases the number of them available to clear LDL from the blood, which reduces LDL cholesterol levels.

Lerochol (lerodalcibep-liga) will be considered for coverage when the following criteria are met:

Heterozygous Familial Hypercholesterolemia (HeFH)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a lipid specialist, cardiologist, or endocrinologist; AND
3. Member has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) confirmed by one of the following:
   a) Genetic testing (presence of LDL-R, ApoB, or PCSK9 mutation)
   b) Dutch Lipid Network score greater than 8 points
   c) "Definite" per Simon Broome criteria (i.e., LDL > 190 mg/dL at baseline AND tendon xanthoma OR LDL-R, ApoB, or PCSK9 mutation); AND
4. Member has a lipid panel within the past 90 days showing LDL of 100 mg/dL or greater; AND
5. Member's LDL is elevated despite at least a 3-month adherent trial of high intensity or max tolerated statin therapy in combination with ezetimibe (unless there is documentation of clearly established statin intolerance or statin contraindication—see note*); AND
6. Lerochol will be used in combination with a statin and/or ezetimibe, unless contraindicated or intolerant; AND
7. Prescriber attests that the member will follow a diet and exercise regimen; AND
8. Lerochol will not be used in combination with any other drug that targets PCSK9.
9. **Dosage allowed/Quantity limit:** 300 mg once monthly administered subcutaneously.
   QL: 1 syringe per 28 days

**Note: If not on statin therapy, member must have documented contraindication to all statin drugs or documentation of intolerance to at least 2 different statins, including low/moderate intensity or alternate dosing such as every other day.*

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes along with recent labs have been provided showing a clinically meaningful reduction of LDL-C level from baseline OR LDL-C is at goal.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Hypercholesterolemia

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Member has one of the following:
   a) Diagnosis of ASCVD (e.g., acute coronary syndromes (ACS), myocardial infarction (MI), stroke, angina, or peripheral arterial disease [PAD])
   b) ASCVD risk factor such as metabolic syndrome, chronic kidney disease, diabetes, or coronary artery calcium (CAC) score >300; AND
3. Member has a lipid panel within the past 90 days showing an LDL of at least 100 OR an LDL >55 with ASCVD and intolerance to Repatha or Praluent; AND
4. Member's LDL elevation is despite at least a 3-month adherent trial of high intensity or max tolerated statin therapy in combination with ezetimibe (unless there is documentation of clearly established statin intolerance or statin contraindication—see note*); AND
5. Lerochol will be used in combination with a statin and/or ezetimibe, unless contraindicated or intolerant; AND
6. Prescriber attests that the member will follow a diet and exercise regimen; AND
7. Lerochol will not be used in combination with any other drug that targets PCSK9.
8. **Dosage allowed/Quantity limit:** 300 mg once monthly administered subcutaneously.
   QL: 1 syringe per 28 days

   **Note: If not on statin therapy, member must have documented contraindication to all statin drugs or documentation of intolerance to at least 2 different statins, including low/moderate intensity or alternate dosing such as every other day.*

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes along with recent labs have been provided showing a clinically meaningful reduction of LDL-C level from baseline OR LDL-C is at goal.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Lerochol (lerodalcibep-liga) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/13/2026	New policy created for Lerochol.
04/17/2026	Added ACC/AHA 2026 reference.

	Hypercholesterolemia (referred to recommendations for inclisiran since it also does not have CV outcomes data): Changed LDL cutoff from 70 to 100 and added LDL 55 cutoff with stipulations (Blumenthal 2026, sections 4.2.4.3 and 4.2.6). Updated ASCVD definition (Blumenthal 2026).

References:

1. Lerochol [prescribing information]. LIB Therapeutics, Inc., 2025.
2. Klug EQ, Llerena S, Burgess LJ, et al. Efficacy and Safety of Lerodalcibep in Patients With or at High Risk of Cardiovascular Disease: A Randomized Clinical Trial. *JAMA Cardiol*. 2024;9(9):800-807. doi:10.1001/jamacardio.2024.1659
3. Raal F, Fourie N, Scott R, et al. Long-term efficacy and safety of lerodalcibep in heterozygous familial hypercholesterolaemia: the LIBerate-HeFH trial. *Eur Heart J*. 2023;44(40):4272-4280. doi:10.1093/eurheartj/ehad596
4. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC Guideline on the Management of Blood Cholesterol. *JACC*. 2018;73(24)doi:10.1016/j.jacc.2018.11.002.
5. McGowen, Dehkordi S, Moriarty P, et al. Diagnosis and treatment of heterozygous familial hypercholesterolemia. *J Am Heart Assoc*. 2019 Dec 17;8(24):e013225.
6. Lloyd-Jones DM, Morris PB, et al. 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee [published correction appears in J Am Coll Cardiol. 2023 Jan 3;81(1):104]. *J Am Coll Cardiol*. 2022;80(14):1366-1418. doi:10.1016/j.jacc.2022.07.006
7. Patel SB, Wyne KL, Afreen S, et al. American Association of Clinical Endocrinology Clinical Practice Guideline on Pharmacologic Management of Adults With Dyslipidemia. *Endocr Pract*. 2025;31(2):236-262. doi:10.1016/j.eprac.2024.09.016
8. Patel SB, Belalcazar LM, Afreen S, et al. American Association of Clinical Endocrinology Consensus Statement: Algorithm for Management of Adults with Dyslipidemia - 2025 Update. *Endocr Pract*. 2025;31(10):1207-1238. doi:10.1016/j.eprac.2025.07.014
9. Blumenthal RS, Morris PB, Gaudino M, 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. *J Am Coll Cardiol*. Published online March 13, 2026. doi:10.1016/j.jacc.2025.11.016

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