Medical Drug Clinical Criteria

Subject:	Lerochol (lerodalcibep-liga)		
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Overview

This document addresses the use of Lerochol (lerodalcibep-liga), a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor approved by the Food and Drug Administration (FDA) as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH). Lerochol is administered once monthly subcutaneously. The effect of Lerochol on cardiovascular morbidity and mortality has not been determined.

Familial hypercholesterolemia is an inherited condition caused by genetic mutations which cause high levels of LDL-C at an early age. There are two types of familial hypercholesterolemia (FH). Heterozygous FH (HeFH) is the more common type occurring in approximately 1 in 200 to 250 individuals. Individuals with HeFH have one altered copy of a cholesterol-regulating gene. Homozygous FH (HoFH) is the rare, more severe form, occurring in approximately 1 in 300,000 to 400,000 individuals. Individuals with HoFH have two altered copies of cholesterol-regulating genes. HoFH can cause LDL-C levels more than six times as high as normal (for example, 650-1,000 mg/dL).

Definitive diagnosis of familial hypercholesterolemia is established by genetic confirmation of one or more mutations in one of the genes critical for LDL-C catabolism. If genetic testing is unavailable, diagnosis can be established though clinical criteria based on LDL-C levels, clinical presentation and family history.

In the clinical setting, statins are considered first-line drug therapy, in addition to healthy lifestyle interventions, in individuals requiring treatment for abnormal cholesterol. Other lipid lowering therapies should be considered second-line options for individuals needing additional cholesterol lowering or who can't tolerate moderate to high doses of statins.

In 2026, the American College of Cardiology (ACC)/American Heart Association (AHA) released updated guidelines on the management of dyslipidemia. In individuals with clinical ASCVD, the guidance recommends intensifying lipid-lowering therapy to achieve LDL-C of less than 70 mg/dL or 55 mg/dL, depending on risk. Ezetimibe, PCSK9 monoclonal antibodies and bempedoic acid are recommended options for add-on to statin therapy to achieve LDL-C reduction.

In individuals with severe primary hypercholesterolemia (baseline LDL-C ≥190 mg/dL) without ASCVD, the guidance recommends an LDL-C goal of 70 mg/dL when additional risk factors, genetic confirmation of familial hypercholesterolemia or subclinical atherosclerosis are present. In individuals with severe primary hypercholesterolemia (baseline LDL-C ≥190 mg/dL) without additional risk as well as other primary prevention populations, the guidance recommends an LDL-C goal of 100 mg/dL. Ezetimibe, PCSK9 monoclonal antibodies and bempedoic acid are recommended options for add-on to statin therapy to achieve LDL-C reduction.

In individuals without a history of clinical ASCVD who experience statin-attributed muscle symptoms on the recommended intensity of statin therapy and are at high ASCVD risk based on the PREVENT-ASCVD equation of ≥10%, a coronary artery calcium (CAC) score ≥300 AU or diabetes, the guidance recommends an LDL-C goal of 70 mg/dL. Ezetimibe, PCSK9 monoclonal antibodies and bempedoic acid are recommended options for add-on to statin therapy to achieve LDL-C reduction.

The 2026 ACC/AHA guideline was developed before the FDA approval for Lerochol, and its role is limited by the absence of cardiovascular outcomes data.

Statins have labeled warnings for liver enzyme abnormalities and skeletal muscle effects including myopathy and rhabdomyolysis. Statin-induced adverse events leading to some degree of intolerance is reported in as many as 5% to 30% of individuals although incidence and prevalence vary. The National Lipid Association (NLA) has provided guidance defining statin intolerance as one or more adverse effects associated with statin therapy, which resolves or improves with dose reduction or discontinuation, and can be classified as complete inability to tolerate any dose of a statin or partial intolerance, with inability to tolerate the dose necessary to achieve the individual-specific therapeutic objective. To classify an individual as having statin intolerance, a minimum of two statins should have been attempted, including at least one at the lowest approved daily dosage.

World Health Organization (WHO)/Dutch Lipid Clinic Network Criteria for Familial Hypercholesterolemia (FH) Diagnosis

Criteria	Points
Family History	
Known premature coronary and vascular disease (men <55 years, women <60 years) in first degree relative	1
Known LDL-C >95th percentile in first degree relative	1
Tendon xanthoma and/or corneal arcus in first degree relative	2
Children aged <18 years with LDL-C >95th percentile	2
Personal Clinical History	
Premature coronary artery disease (men <55 years, women <60 years)	2
Premature cerebral or peripheral vascular disease (men <55 years, women <60 years)	1
Clinical Exam	
Tendon xanthoma	6
Corneal arcus in individual aged <45 years	4
LDL-C Level	
> 329 mg/dL (>8.5 mmol/L)	8
250-329 mg/dL (6.5-8.4 mmol/L)	5
190-249 mg/dL (5.0-6.4 mmol/L)	3
155-189 mg/dL (4.0-4.9 mmol/L)	1
Genetic Testing	
Functional mutation in LDLR, ApoB or PCSK9 gene	8

Scoring: Definite FH:> 8 points; Probable FH: 6-8 points; Possible FH: 3-5 points; Unlikely FH: 0-2 points.

Clinical Criteria

Lerochol (lerodalcibep-liga)

Initial requests for Lerochol (lerodalcibep-liga) may be approved when the following criteria are met:

I. Individual is at high risk for atherosclerotic cardiovascular disease (ASCVD) events as identified by one of the following:
   A. Individual has Heterozygous Familial Hypercholesterolemia (HeFH) verified by (Singh 2015; WHO 1999):
      1. Presence of a mutation in LDLR, ApoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene; **OR**
      2. WHO/Dutch Lipid Clinic Network criteria with score of greater than eight points; **OR**
   B. Individual has a history of clinical atherosclerotic cardiovascular disease (ASCVD) including one or more of the following (2026 ACC/AHA):
      1. Acute coronary syndrome;
      2. Coronary artery disease (CAD);
      3. History of myocardial infarction (MI);
      4. Stable or unstable angina;
      5. Coronary or other arterial revascularization;
      6. Stroke;
      7. Transient ischemic attack (TIA);
      8. Peripheral arterial disease (PAD); **OR**
   C. Individual has hypercholesterolemia;

AND

II. Individual meets one of the following:

A. Individual is on high intensity statin therapy or statin therapy at the maximum tolerated dose (high intensity statin is defined as atorvastatin 40 mg or higher or rosuvastatin 20 mg or higher) (2026 ACC/AHA); **OR**
B. Individual is statin intolerant based on one of the following:
    1. Inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, demonstrated by adverse effects associated with statin therapy that resolve or improve with dose reduction or discontinuation (NLA 2022); **OR**
    2. Statin associated rhabdomyolysis or immune-mediated necrotizing myopathy (IMNM) after a trial of one statin; **OR**
C. Individual has a contraindication for statin therapy including but not limited to active liver disease, unexplained persistent elevation of hepatic transaminases or pregnancy;

AND

III. Individual meets one of the following (2026 ACC/AHA):
A. Individual has LDL-C greater than or equal to 55 mg/dL; AND
    1. Individual has a history of clinical ASCVD; OR
B. Individual has LDL-C greater than or equal to 70 mg/dL; AND
    1. Individual has severe hypercholesterolemia (baseline LDL greater than or equal to 190 mg/dL) AND HeFH, additional ASCVD risk factors or coronary calcification; OR
    2. Individual has PREVENT-ASCVD equation of ≥10%; OR
    3. Individual has coronary artery calcium (CAC) greater than or equal to 300 AU; OR
    4. Individual has a diagnosis of diabetes; OR
C. Individual has LDL-C greater than or equal to 100 mg/dL.

Continuation requests for Lerochol (lerodalcibep-liga) may be approved when the following criteria are met:

I. Individual continues to use in combination with maximally tolerated statin therapy (unless contraindication or individual is statin intolerant); **AND**
II. Individual has achieved LDL-C reduction.

Lerochol (lerodalcibep-liga) may not be approved for the following:
I. In combination with Leqvio, Praluent or Repatha; **OR**
II. When the above criteria are not met and for all other indications.

Initial Approval Duration: 1 year
Continuation Approval Duration: 1 year

Step Therapy

Note: When Lerochol (lerodalcibep-liga) is deemed approvable based on the clinical criteria above, the benefit plan may have additional criteria requiring the use of a preferred[1] agent or agents.

Non-Preferred PCSK9 Agent Step Therapy

A list of the preferred PCSK9 agents is available here.

Requests for a non-preferred PCSK9 agent may be approved if the following criterion is met:

I. Individual has had an adequate trial and titration of a preferred PCSK9 agent and achieved suboptimal lipid lowering response.

[1]Preferred, as used herein, refers to agents that were deemed to be clinically comparable to other agents in the same class or disease category but are preferred based upon clinical evidence and cost effectiveness.

Quantity Limits

Lerochol (lerodalcibep-liga) Quantity Limit

Drug	Limit
Lerochol (lerodalcibep-liga) 300 mg/1.2 mL prefilled syringe	1 syringe per 28 days

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [when specified as Lerochol (lerodalcibep-liga)]
J3590	Unclassified biologics [when specified as Lerochol (lerodalcibep-liga)]

ICD-10 Diagnosis

E10.10-E10.A2	Type 1 diabetes mellitus
E11.00-E11.A	Type 2 diabetes mellitus
E13.00-E13.9	Other specified diabetes mellitus
E78.0	Pure hypercholesterolemia
E78.011	Heterozygous familial hypercholesterolemia [HeFH]
E78.1	Pure hyperglyceridemia
E78.2	Mixed hyperlipidemia
E78.41-E78.5	Other, unspecified hyperlipidemia
G45.0-G45.9	Transient cerebral ischemic attacks and related syndromes
I20.0-I20.9	Angina pectoris
I21.01-I21.B	Acute myocardial infarction
I22.0-I22.9	Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I23.7	Postinfarction angina
I24.0-I24.9	Other acute ischemic heart disease
I25.10-I25.9	Chronic ischemic heart disease
I63.00-I63.9	Cerebral infarction
I65.01-I65.9	Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction
I66.01-I66.9	Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction
I67.2	Cerebral atherosclerosis
I67.82	Cerebral ischemia
I69.00-I69.998	Sequelae of cerebrovascular disease
I70.0-I70.92	Atherosclerosis
I73.9	Peripheral vascular disease, unspecified
Z83.42	Family history of familial hypercholesterolemia
Z86.73	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits
Z95.1	Presence of aortocoronary bypass graft
Z95.5	Presence of coronary angioplasty implant and graft
Z95.820-Z95.828	Presence of other vascular implants and grafts
Z98.61-Z98.62	Angioplasty status

Document History

Revised: 5/15/2026
Document History:

- 5/15/2026 – Annual Review: Update indication wording and LDL threshold criteria. Update guideline reference. Step therapy table updates. Coding Reviewed: Removed HCPCS NOC J3490 and added J3590. Added ICD-10-CM E10.10-E10.A2, E11.00-E11.A, E13.00-E13.9.
- 06/01/2026 – Step therapy table updates.
- 05/01/2026 – Add step therapy and step therapy tables.
- 2/20/2026 – Select Review: New clinical criteria and quantity limit for Lerochol. Coding Reviewed: Added HCPCS NOC C9399 and J3490 for Lerochol. Added ICD-10-CM E78.00, E78.011, E78.1, E78.2, E78.41-E78.5, G45.0-G45.9, I20.0-I20.9, I21.01-I21.B, I22.0-I22.9, I23.7, I24.0-I24.9, I25.10-I25.9, I63.00-I63.9, I65.01-I65.9, I66.01-I66.9, I67.2, I67.82, I69.00-I69.998, I70.0-I70.92, I73.9, Z83.42, Z86.73, Z95.1, Z95.5, Z95.820-Z95.828, Z98.61, Z98.62.

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Lerochol CC-0299

Commercial Medical Benefit

Effective Date	Preferred Agent	Non-Preferred Agent
08/01/2026	Praluent Repatha	Lerochol

Medicaid Medical Benefit

Effective Date	Preferred Agent	Non-Preferred Agent
06/01/2026: FL Healthy Kids, MD, NY, WNY 07/01/2026: DC, GA	Repatha	Lerochol

Medicare Medical Benefit

Effective Date	Preferred Agent	Non-Preferred Agent
N/A	N/A	N/A