

Drug Policy

Policy:	Lerochol™ (Ierodalcibep-liga subcutaneous injection – LIB)	Annual Review Date: 06/18/2026 Last Revised Date: 06/18/2026
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OVERVIEW

Lerochol, a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor, is indicated to **reduce low-density lipoprotein cholesterol (LDL-C)**, as an adjunct to diet and exercise, in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH) in adults.¹

Praluent® (alirocumab subcutaneous injection) and Repatha® (evolocumab subcutaneous injection) are two other PCSK9 inhibitors.^{2,3} Leqvio® (inclisiran subcutaneous injection), a small interfering ribonucleic acid messenger RNA, is a similar product.⁴

POLICY STATEMENT

This policy involves the use of Rhapsido. Prior authorization is recommended for pharmacy benefit coverage of Rhapsido. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Rhapsido as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Rhapsido be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rhapsido is recommended in those who meet the following criteria:

1. **Heterozygous Familial Hypercholesterolemia (HeFH).*** Approve for 1 year if the patient meets ONE of the following (A or B):
 - A) **Initial Therapy.** Approve if the patient meets ALL of the following (i, ii, and iii):
 - i. Patient is ≥ 18 years of age; AND
 - ii. Patient meets ONE of the following (a, b, or c):
 - a) Patient has an untreated low-density lipoprotein cholesterol (LDL-C) ≥ 190 mg/dL (prior to treatment with antihyperlipidemic agents); OR
 - b) The diagnosis has been confirmed by genetic testing; OR

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Note: Examples include pathogenic variants at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene.

- c) Patient has been diagnosed with heterozygous familial hypercholesterolemia by meeting ONE of the following diagnostic criteria thresholds [(1) or (2)]:
 - (1) Prescriber confirms that the Dutch Lipid Network criteria score was > 5; OR
 - (2) Prescriber confirms that Simon Broome criteria met the threshold for “definite” or “possible (or probable)” familial hypercholesterolemia; AND

iii. Patient meets ONE of the following (a or b):

- a) Patient meets BOTH of the following [(1) and (2)]:
 - (1) Patient has tried one high-intensity statin therapy (i.e., atorvastatin ≥ 40 mg daily; rosuvastatin ≥ 20 mg daily [as a single-entity or as a combination product]) for ≥ 8 continuous weeks; AND
 - (2) LDL-C level after this treatment remains ≥ 70 mg/dL; OR
- b) Patient has been determined to be statin intolerant by meeting ONE of the following [(1) or (2)]:
 - (1) Patient experienced statin-related rhabdomyolysis; OR

Note: Rhabdomyolysis is statin-induced muscle breakdown that is associated with markedly elevated creatine kinase levels (at least 10 times the upper limit of normal), along with evidence of end organ damage which can include signs of acute renal injury (noted by substantial increases in serum creatinine [Scr] levels [a ≥ 0.5 mg/dL increase in Scr or doubling of the Scr] and/or myoglobinuria [myoglobin present in urine]).

- (2) Patient meets ALL of the following [(a), (b), and (c)]:
 - (a) Patient experienced skeletal-related muscle symptoms; AND
 - Note: Examples of skeletal-related muscle symptoms include myopathy (muscle weakness) or myalgia (muscle aches, soreness, stiffness, or tenderness).
 - (b) The skeletal-muscle related symptoms occurred while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or combination products); AND
 - (c) When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products), the skeletal-related muscle symptoms resolved upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin); OR

Note: Examples of skeletal-related muscle symptoms include myopathy and myalgia.

- B) Patient is Currently Receiving Lerochol. Approve if according to the prescriber, the patient has experienced a response to therapy.

Note: Examples of a response to therapy include decreasing LDL-C, total cholesterol, non-high-density lipoprotein, or apolipoprotein B levels. Also, if the patient is currently receiving the requested therapy but has not previously received approval of Lerochol for this specific indication through the Coverage Review Department, review under criteria for Initial Therapy. If the patient is restarting therapy with Lerochol, Initial Therapy criteria must be met.

2. **Hypercholesterolemia.*** Approve for 1 year if the patient meets ONE of the following (A or B):

Note: This diagnosis is not associated with established cardiovascular disease/reduce major adverse cardiovascular events for patients at increased risk, heterozygous familial hypercholesterolemia (HeFH), or homozygous familial hypercholesterolemia (HoFH) and may be referred to as combined hyperlipidemia, primary hyperlipidemia, dyslipidemia, or increased/elevated low-density lipoprotein cholesterol (LDL-C) levels.

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- A) **Initial Therapy.** Approve if the patient meets ALL of the following (i, ii, and iii):
- i. Patient is ≥ 18 years of age; AND
 - ii. Patient meets ONE of the following (a or b):
 - a) According to the prescriber, the patient is at risk for atherosclerotic cardiovascular disease (ASCVD), an ASCVD event, or a major adverse cardiovascular event (MACE); OR
 - b) Patient has diabetes; AND
 - iii. Patient meets ONE of the following (a or b):
 - a) Patient meets ALL of the following [(1) and (2)]:
 - (1) Patient has tried one high-intensity statin therapy (i.e., atorvastatin ≥ 40 mg daily; rosuvastatin ≥ 20 mg daily [as a single-entity or as a combination product]); AND
 - (2) LDL-C level after this treatment regimen remains ≥ 70 mg/dL; OR
 - b) Patient has been determined to be statin intolerant by meeting ONE of the following [(1) or (2)]:
 - (1) Patient experienced statin-related rhabdomyolysis; OR
Note: Rhabdomyolysis is statin-induced muscle breakdown that is associated with markedly elevated creatine kinase levels (at least 10 times the upper limit of normal), along with evidence of end organ damage which can include signs of acute renal injury (noted by substantial increases in serum creatinine [Scr] levels [$a \geq 0.5$ mg/dL increase in Scr or doubling of the Scr] and/or myoglobinuria [myoglobin present in urine]); OR
 - (2) Patient meets ALL of the following [(a), (b), and (c)]:
 - (a) Patient experienced skeletal-related muscle symptoms; AND
Note: Examples of skeletal-related muscle symptoms include myopathy (muscle weakness) or myalgia (muscle aches, soreness, stiffness, or tenderness).
 - (b) The skeletal-muscle related symptoms occurred while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or combination products); AND
 - (c) When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products), the skeletal-related muscle symptoms resolved upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin); OR
Note: Examples of skeletal-related muscle symptoms include myopathy and myalgia.
- B) **Patient is Currently Receiving Lerochol.** Approve if according to the prescriber, the patient has experienced a response to therapy.
Note: Examples of a response to therapy include decreasing LDL-C, total cholesterol, non-high-density lipoprotein, or apolipoprotein B levels. Also, if the patient is currently receiving the requested therapy but has not previously received approval of Lerochol for this specific indication through the Coverage Review Department, review under criteria for Initial Therapy. If the patient is restarting therapy with Lerochol, Initial Therapy criteria must be met.

Note:

* A patient may have a diagnosis that pertains to more than one FDA-approved indication, therefore, consider review under different approval conditions, if applicable (e.g., a patient with heterozygous familial hypercholesterolemia may have hypercholesterolemia and a patient with hypercholesterolemia may have heterozygous familial hypercholesterolemia).

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Initial Approval/ Extended Approval.

A) *Initial Approval:* 1 year

B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Rhapsido has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concurrent use of Lerochol with Praluent (alirocumab subcutaneous injection), Repatha (evolocumab subcutaneous injection), or Leqvio (inclisiran subcutaneous injection).** Praluent and Repatha are PCSK9 inhibitors and should not be used with Lerochol.^{2,3} Leqvio, a small interfering ribonucleic acid (RNA) directed to PCSK9 messenger RNA, is a similar product and should not be given with Lerochol.⁴
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.

Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Rhapsido® tablets [prescribing information]. East Hanover, NJ: Novartis; September 2025.
2. Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. *Allergy*. 2022;73:734-766.