Department:	Pharmacy Management	**Original Approval:**	06/28/2022
Policy No:	PM181	**Last Approval:**	05/15/2026
Policy Title:	Inclisiran (Leqvio) Clinical Coverage Criteria		
Approved By:	UM Criteria Subcommittee		
Applicable Line(s) of Business:	☒ **Washington Apple Health (Medicaid)** ☐ **Behavioral Health Services Only** ☒ **Apple Health Expansion** ☒ **Medicare Advantage/Special Needs Plan** ☒ **Medicare Advantage Only** ☒ **Cascade Select**		

Required Clinical Documentation for Review

Documentation required to determine medical necessity for Leqvio (inclisiran):

- History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service
- Diagnosis
- Labs/Diagnostics
- Dosing and duration requested
- Initial/Extended approval
- Medical records from the last 6 months showing the patient's problems, history, prior treatments, response to treatment, imaging and laboratory studies, details of the skilled needs, details of any specific needs related to risk/trauma/cultural etc., assessment and plan
- Prescribed by or in consultation with a specialist, when indicated

Background

Leqvio, a small interfering ribonucleic acid (RNA) directed to proprotein convertase subtilisin kexin type 9 (PCSK9) messenger RNA, is indicated as an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C).[1] The safety and effectiveness have not been established in pediatric patients.

Dosing Information

Leqvio is given as a subcutaneous injection and should be administered by a healthcare professional. The dose is 284 mg given as a single subcutaneous injection initially, again at 3 months, and then once every 6 months.

Guidelines

Many guidelines are available regarding the treatment of patients with dyslipidemia which include the management of HeFH and atherosclerotic cardiovascular disease (ASCVD).[2-10] For patients with elevated LDL-C, statins are the cornerstone of therapy and recommended first-line to be used at maximally tolerated doses due to the established benefits regarding the reduction of cardiovascular (CV) risks. Atorvastatin 40 mg to 80 mg once daily (QD) and rosuvastatin 20 mg to 40 mg QD are considered high-intensity statins as they achieve LDL-C lowering of ≥ 50%.

- The **American College of Cardiology (ACC) Expert Consensus Decision Pathway on the Role of Non-Statin Therapies** for LDL-C Lowering in the Management of ASCVD Risk (2022) make several recommendations regarding PCSK9 inhibitors and Leqvio.[2] For adults with clinical ASCVD at very high risk (e.g., patients with major ASCVD events, HeFH, diabetes) who are on statin therapy for secondary prevention, the general goal is ≥ 50% LDL-C reduction and an LDL-C < 55 mg/dL with maximally tolerated statin therapy. If the above goals are not achieved, the initial non-statin agents recommended include ezetimibe and/or a PCSK9 monoclonal antibody (i.e., Repatha® [evolocumab subcutaneous injection] or Praluent® [alirocumab subcutaneous injection]). Leqvio may also be considered.
- **The American Heart Association (AHA)/ACC guidelines for chronic coronary disease (2023)** state that in patients with chronic coronary disease on maximally tolerated statin therapy who have an LDL-C level ≥ 70 mg/dL, and in whom ezetimibe and PCSK9 inhibitors are deemed insufficient or not tolerated, it may be reasonable to add Nexletol® (bempedoic acid tablets) or Leqvio (in place of a PCSK9 inhibitor) to further reduce LDL-C levels.[10]
- **The AHA** published a scientific statement regarding familial hypercholesterolemia (2015).[8] Key points are that the condition may start early (in childhood or adolescence) and is noted by LDL-C levels ≥ 190 mg/dL. Premature CV disease can result. Diagnosis can be confirmed by genetic testing. The Dutch Lipid Clinic Network criteria and Simon Broome criteria may also be used which incorporate cholesterol levels, family history, clinical findings, and physical manifestations. Aggressive lipid-lowering therapy is recommended to achieve LDL-C reductions of at least 50%.

Definitions

1. Highest-tolerated statin dose is defined as ONE of the following:
   A) FDA labeled maximum dose for high-intensity statin therapy (e.g. atorvastatin 40 to 80mg and rosuvastatin 20 to 40 mg)
   B) Client is adherent to a statin with documentation supporting intolerance to at least two other statins

C) Treatment with statin therapy is contraindicated or not tolerated (statin intolerance is defined below)
D) Clients who have statin intolerance are not required to use ezetimibe prior to a PCSK-9 inhibitor

2. Statin in tolerance is defined as the following:
   A) Documented trial and failure of at least two statins after ruling out hypothyroidism, changes in physical activity and exercise, and potential drug-drug interactions, due to pre-specified intolerance symptoms (e.g., myopathy, myalgia, myositis) that began or increased during statin therapy and stopped when statin therapy was discontinued. Qualification of at least two statins is: one statin must be at lowest starting daily dose and a different statin may be at any dose.
   B) If patient is on combination therapy, such as a fibrate or niacin, discontinuing fibrate or niacin while maintaining statin therapy is required to establish statin intolerance.
   C) Rhabdomyolysis determined to be caused by any statin at any dose, after ruling out all other potential causes including drug-drug interactions, will be considered as a contraindication to statins as a class. Patients with history of rhabdomyolysis caused by statins must be managed by, or in consultation with, a specialist, and may be considered eligible for PCSK-9 Inhibitors on a case-by-case basis.

Indications/Criteria

Medicaid Members	***Preferred Products: Repatha, Leqvio*** ***Non-Preferred Product: Praluent***
Individual & Family (Cascade Select) Members	***Preferred Products: Praluent, Repatha*** ***Non-Preferred Products: Leqvio***
Medicare Members	***Preferred Products: Praluent, Repatha*** ***Non-Preferred Product: Leqvio***

Medicaid Criteria

1. **Primary Hypercholesterolemia/Heterozygous Familial Hypercholesterolemia (HeFH)**. Approve for 6 months if the patient meets all of the following (A, B, C, D, and E):
   A) Diagnosis of primary hypercholesterolemia OR heterozygous familial hypercholesterolemia defined by ONE of the following (i or ii):
   i. Clinical diagnosis using diagnostic tools such as US MedPed, Simon Broome Register Group, or Dutch Lipid Panel; OR
   ii. Genetic typing confirming presence of familial hypercholesterolemia genes; AND

B) Concomitant therapy with the highest-tolerated statin dose (see definitions below) and ezetimibe for at least 6 consecutive weeks AND ONE of the following (i, ii, or iii):
- **i.** LDL has not achieved at least 50% reduction from baseline; OR
- **ii.** Inability to achieve LDL cholesterol level <100 mg/dL; OR
- **iii.** For adults with known coronary heart disease or diabetes, inability to achieve LDL cholesterol level <70 mg/dL; AND

C) Patient is ≥ 18 years of age; AND
D) Not used in combination with another PCSK-9 inhibitor; AND

Dosing. Approve ONE of the following dosage regimens (A or B):
- **A)** Initial dose is 284 mg given as a single subcutaneous injection, again at 3 months, and then once every 6 months; OR
- **B)** Maintenance dose is 284 mg given as a subcutaneous injection once every 6 months.

If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.

Reauthorization. Approve for 12 months in patients who meet ALL the following conditions (A and B):
- **A)** Continues to receive the maximum tolerated dose of statin unless contraindicated or intolerant to statin therapy; AND
- **B)** Documentation of continued clinical benefit, (e.g. at least a 30% reduction in LDL from initiation of PCSK-9 Inhibitor or achievement of patient-specific goal).

If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be forwarded to a CHPW Medical Director or CHPW pharmacist on a case-by-case basis up to the initial authorization duration.

Cascade Select and Medicare Criteria

FDA-Approved Indications

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, iii, and iv):
- **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) level ≥ 190 mg/dL (prior to treatment with antihyperlipidemic agents); OR

b) Patient has phenotypic confirmation of heterozygous familial hypercholesterolemia; OR

Note: Examples include pathogenic variants at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), 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 meeting one of the following diagnostic criteria thresholds [(1) or (2)]:

(1) Prescribing physician confirms that the Dutch Lipid Network criteria score was > 5; OR

(2) Prescribing physician confirms that Simone 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 all of the following [(1), (2), and (3)]:

(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) Patient has tried one high-intensity statin along with ezetimibe (as a single-entity or as a combination product) for ≥ 8 continuous weeks; AND

(3) 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 ≥ 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); AND
Note: Examples of skeletal-related muscle symptoms include myopathy and myalgia.

iv. Patient meets one of the following (a or b):
- **a)** Patient meets both of the following both of the following [(1) and (2)]:
  - **(1)** Patient has tried at least one proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor; AND
    Note: Examples of PCSK9 inhibitors include Praluent and Repatha.
  - **(2)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR
- **b)** The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days; OR

B) Patient Currently Receiving Leqvio. Approve if the patient meets all of the following (i and ii):

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

ii. Patient meets one of the following (a or b):
- **a)** Patient meets both of the following both of the following [(1) and (2)]:
  - **(1)** Patient has tried at least one proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor; AND
    Note: Examples of PCSK9 inhibitors include Praluent and Repatha.
  - **(2)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR
- **b)** The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days.

Dosing. Approve ONE of the following dosage regimens (A or B):

A) Initial dose is 284 mg given as a single subcutaneous injection, again at 3 months, and then once every 6 months; OR

B) Maintenance dose is 284 mg given as a subcutaneous injection once every 6 months.

2. Primary Hyperlipidemia.* Approve for 1 year if the patient meets ONE of the following (A or B): Note: This is not associated with atherosclerotic cardiovascular disease (ASCVD) or

heterozygous familial hypercholesterolemia (HeFH) and may be referred to as combined hyperlipidemia, hypercholesterolemia (pure, primary), dyslipidemia, or increased/elevated low-density lipoprotein cholesterol (LDL-C) levels.

A) Initial Therapy. Approve if the patient meets all of the following (i, ii, iii, and iv):

- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient meets ONE of the following (a or b):
  - **a)** Patient has a coronary artery calcium or calcification score ≥ 300 Agatston units; OR
  - **b)** Patient has diabetes; AND
- **iii.** Patient meets one of the following (a or b):
  - **a)** Patient meets all of the following [(1]), (2), and (3)]:
    - **(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)** Patient has tried the one high-intensity statin therapy above along with ezetimibe (as a single-entity or as a combination product) for ≥ 8 continuous weeks; AND
    - **(3)** LDL-C level after this treatment regimen remains ≥ 100 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); AND

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

iv. Patient meets one of the following (a or b):

a) Patient meets both of the following [(1) or (2)]:

(1) Patient has tried at least one proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor; AND

Note: Examples of PCSK9 inhibitors include Praluent and Repatha.

(2) Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; OR

b) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days; OR

B) Patient Currently Receiving Leqvio. Approve if the patient meets all of the following (i and ii):

i. According to the prescribing physician, the patient has experienced a response to therapy; AND

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

ii. Patient meets one of the following (a or b):

a) Patient meets both of the following [(1) or (2)]:

(1) Patient has tried at least one proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor; AND

Note: Examples of PCSK9 inhibitors include Praluent and Repatha.

(2) Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; Or

b) The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days.

Dosing. Approve ONE of the following dosage regimens (A or B):

A) Initial dose is 284 mg given as a single subcutaneous injection, again at 3 months, and then once every 6 months; OR

B) Maintenance dose is 284 mg given as a subcutaneous injection once every 6 months.

Other Uses with Supportive Evidence

3. Established Cardiovascular Disease.* 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, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient has had one of the following conditions or diagnoses (a, b, c, d, e, or f):

a) A previous myocardial infarction or a history of an acute coronary syndrome; OR

b) Angina (stable or unstable); OR

c) A past history of stroke or transient ischemic attack; OR

d) Coronary artery disease; OR

e) Peripheral arterial disease; OR

f) Patient has undergone a coronary or other arterial revascularization procedure in the past; AND

Note: Examples include coronary artery bypass graft surgery, percutaneous coronary intervention, angioplasty, and coronary stent procedures.

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

a) Patient meets all of the following ([(1), (2), and (3)]:

(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) Patient has tried one high-intensity statin along with ezetimibe (as a single-entity or as a combination product) for ≥ 8 continuous weeks; AND

(3) Low-density lipoprotein cholesterol (LDL-C) level after this treatment regimen remains ≥ 55 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); AND
Note: Examples of a response to therapy include decreasing LDL-C, total cholesterol, non-high-density lipoprotein (non-HDL-C), or apolipoprotein B levels. Also, if the patient is currently receiving the requested therapy but has not previously received approval of Leqvio for this specific indication through the Coverage Review Department, review under criteria for Initial Therapy. If the patient is restarting therapy with Leqvio, Initial Therapy criteria must be met.

iv. Patient meets one of the following (a or b):
- **a)** Patient meets both of the following [(1) or (2)]:
  - **(1)** Patient has tried at least one proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor; AND
  Note: Examples of PCSK9 inhibitors include Praluent and Repatha.
  - **(2)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; Or
- **b)** The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days.

B) Patient Currently Receiving Leqvio. Approve if the patient meets all of the following (i and ii):

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

ii. Patient meets one of the following (a or b):
- **a)** Patient meets both of the following [(1) or (2)]:
  - **(1)** Patient has tried at least one proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor; AND
  Note: Examples of PCSK9 inhibitors include Praluent and Repatha.
  - **(2)** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber; Or
- **b)** The patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days.

Dosing. Approve ONE of the following dosage regimens (A or B):

A) Initial dose is 284 mg given as a single subcutaneous injection, again at 3 months, and then once every 6 months; OR

B) Maintenance dose is 284 mg given as a subcutaneous injection once every 6 months.

Note:

* A patient may have a diagnoses that pertains to more than one indication, therefore, consider review under different approval conditions, if applicable (e.g., a patient with heterozygous familial hypercholesterolemia may have had a clinical ASCVD event, a patient with primary hyperlipidemia may have heterozygous familial hypercholesterolemia).

Conditions Not Recommended for Approval

Coverage of Leqvio is not recommended in the following situations:

1. **Concurrent use of Leqvio with Repatha (evolocumab subcutaneous injection) or Praluent (alirocumab subcutaneous injection).** Repatha and Praluent are PCSK9 inhibitors and should not be used with Leqvio due to a similar mechanism of action.[1] Patients receiving PCSK9 inhibitors were excluded from the pivotal trials with Leqvio.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Limitations/Exclusions

Please see link to member coverage documents below:

Line of Business	Link to Member Coverage Documents
Medicare Advantage Plans (Including D-SNP)	https://medicare.chpw.org/ Select the appropriate plan from the "Plans" drop down on the top navigation bar.
Apple Health	https://www.chpw.org/for-members/benefits-and-coverage-imc/
Individual & Family (Cascade Select)	https://chnwhealthinsurance.chpw.org/member-center/plan-benefits/

Citations & References

CFR	42 CFR § 438.210
WAC	WAC 284-43-2050

RCW		
LOB & Contract Citation	☒ **WAHIMC** ☐ **BHSO** ☐ **Wraparound** ☐ **SMAC** ☐ **HH**	IMC Section 11.3: Medical Necessity Determination
	☒ **AHE**	AHE Section 11.3: Medical Necessity Determination
	☒ **MA/DSNP**	P&P supports all LOB requirements
	☒ **CS**	P&P supports all LOB requirements
Other Requirements		
NCQA Elements		
References	1. Leqvio® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; June 2024. 2. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2022 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk. *J Am Coll Cardiol*. 2022;80(14):1366-1418. 3. Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice guidelines. *Circulation*. 2014;129(25 Suppl 2):S1-S45. 4. Grundy SM, Stone NJ, Bailey AL, et al. AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol. A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2019;139:e1082-e1143. 5. Newman CB, Blaha MJ, Boord JB, et al. Lipid management in patients with endocrine disorders: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2020;105(12):3613-3682. 6. Jacobson TA, Ito MK, Maki KC, et al. National Lipid Association recommendations for patient-centered management of dyslipidemia: Part 1-full report. *J Clin Lipidol*. 2015;9:129-169.	

	7. Goldberg AC, Hopkins PN, Toth PP, et al. Familial hypercholesterolemia: screening, diagnosis and management of pediatric and adult patients. *J Clin Lipidol*. 2011;5:S1-S8. 8. Gidding SS, Champagne MA, de Ferranti SD, et al. The agenda for familial hypercholesterolemia. A scientific statement from the American Heart Association. *Circulation*. 2015;132(22):2167-2192. 9. Haase A, Goldberg AC. Identification of people with heterozygous familial hypercholesterolemia. *Curr Opin Lipidol*. 2012;23:282-289. 10. Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA guideline for the management of patients with chronic coronary disease: a report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2023 July 14. [Online ahead of print].

Revision History

Revision Date	Revision Description	Revision Made By
05/05/2022	New policy	Alan Gabot, PharmD
06/28/2022	Approval	UM Committee
03/01/2023	Annual review. No criteria updates.	Alan Gabot, PharmD
03/02/2023	Approval	UM Pharmacy Subcommittee
12/26/2023	Annual review. Updated background information. Updated indications to now cover atherosclerotic cardiovascular disease, heterozygous familial hypercholesterolemia, and primary hyperlipidemia. Medicaid member must now have a history of failure, contraindication, or intolerance to Repatha. Cascade Select and Medicare members must now try and fail either Repatha or Praluent.	Alan Gabot, PharmD
01/10/2024	Approval	UM Criteria Subcommittee
07/09/2024	Early update. Updated criteria for Medicaid LOB to match the criteria from HCA Medical Policy No. 39.35.00-3 (Antihyperlipidemics – PCSK-9 Inhibitors). Leqvio will only be covered for primary	Alan Gabot, PharmD

	hypercholesterolemia/Heterozygous Familial Hypercholesterolemia indication under Medicaid.	
07/10/2024	Approval	UM Criteria Subcommittee
09/10/2024	Early update. The requirement that the medication is prescribed by, or in consultation with a cardiologist; an endocrinologist; or a physician who focuses in the treatment of cardiovascular risk management and/or lipid disorders was removed. A patient with diabetes now qualifies for primary hyperlipidemia (if requirements are met). For Heterozygous Familial Hypercholesterolemia, updated mutation criteria to state the following: Patient has phenotypic confirmation of heterozygous familial hypercholesterolemia. Listed examples of phenotypes. Name of indication was changed from "Atherosclerotic Cardiovascular Disease" to Established Cardiovascular Disease".	Alan Gabot, PharmD
09/11/2024	Approval	UM Criteria Subcommittee
05/20/2025	Annual review. No changes	Michael Tom, PharmD
07/09/2025	Approval	UM Criteria Subcommittee
05/14/2026	Early update. For Cascade Select and Medicare, added the following criteria as an option for approval in addition to trying at least one PCSK9 inhibitor: the patient is currently taking the requested Non-Preferred Product OR has previously taken the requested Non-Preferred Product within the past 365 days. For Medicaid, removed the criterion to try and fail Repatha.	Alan Gabot, PharmD
05/15/2026	Approval	UM Criteria Subcommittee

APPENDIX A

Simon Broome Register Diagnostic Criteria.[9]

Definite Familial Hypercholesterolemia
Raised cholesterol
--Total cholesterol greater than 6.7 mmol/L (260 mg/dL) or LDL-C > 4.0 mmol/L (155 mg/dL) in a patient < 16 years of age; OR
--Total cholesterol > 7.5 mmol/L (290 mg/dL) or LDL-C > 4.9 mmol/L (190 mg/dL) in a patient > 16 years of age;
AND
--Tendon xanthomas in the patient or in a first (parent, sibling, or child) or second-degree relative (grandparent, aunt, or uncle);
OR
DNA-based evidence of LDL-receptor, familial defective APOB, or PCSK9 mutation.
Possible (or Probable) Familial Hypercholesterolemia
Raised cholesterol
--Total cholesterol greater than 6.7 mmol/L (260 mg/dL) or LDL-C > 4.0 mmol/L (155 mg/dL) in a patient < 16 years of age; OR
--Total cholesterol > 7.5 mmol/L (290 mg/dL) or LDL-C > 4.9 mmol/L (190 mg/dL) in a patient > 16 years of age;
AND
Family history of premature myocardial infarction younger than 50 years of age in second-degree relative or younger than 60 years of age in first-degree relative;
OR
Raised cholesterol
--Total cholesterol greater than 6.7 mmol/L (260 mg/dL) or LDL-C > 4.0 mmol/L (155 mg/dL) in a patient < 16 years of age; OR
--Total cholesterol > 7.5 mmol/L (290 mg/dL) or LDL-C > 4.9 mmol/L (190 mg/dL) in a patient > 16 years of age;
AND
Family history of raised cholesterol > 7.5 mmol (290 mg/dL) in adult first-degree or second-degree relative or > 6.7 mmol/L (260 mg/dL) in child or sibling aged < 16 years.

LDL-C – Low-density lipoprotein cholesterol; LDL – Low-density lipoprotein; APOB – Apolipoprotein B; PCSK9 – Proprotein convertase subtilisin kexin type 9.

APPENDIX B.

Dutch Lipid Network Criteria.[8]

Criteria	Score
Family History	
First-degree relative with known premature coronary and/or vascular disease (men < 55 years, women < 60 years)	1
First degree relative with known LDL-C > 95th percentile for age and sex	1
First-degree relative with tendon xanthomata and/or arcus cornealis, OR	2
Patient is < 18 years of age with LDL-C > 95th percentile for age and sex	2
Clinical History	
Patient with premature CAD (age as above)	2
Patient with premature cerebral or peripheral vascular disease (age as above)	1
Physical Examination	
Tendon xanthomas	6
Arcus cornealis at age < 45 years	4
LDL-C	
LDL-C ≥ 8.5 mmol/L (330 mg/dL)	8
LDL-C 6.5 to 8.4 mmol/L (250 to 329 mg/dL)	5
LDL-C 5.0 to 6.4 mmol/L (190 to 249 mg/dL)	3
LDL-C 4.0 to 4.9 mg/dL (155 to 189 mg/dL)	1
DNA Analysis	
Functional mutation LDLR, APOB or PCSK9 gene	8
Stratification	**Total score**
Definite familial hypercholesterolemia	> 8
Probable familial hypercholesterolemia	6 to 8
Possible familial hypercholesterolemia	3 to 5
Unlikely familial hypercholesterolemia	< 3

LDL-C – Low-density lipoprotein cholesterol; CAD – Coronary artery disease; LDLR – Low-density lipoprotein receptor; APOB – Apolipoprotein B; PCSK9 – Proprotein convertase subtilisin kexin type 9.