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PCSK9 (REQUIRES PREAUTHORIZATION)

X.64

X.64 PCSK9 (REQUIRES PREAUTHORIZATION)

POLICY

Target Agents:

Praluent® (alirocumab) is FDA approved for:

- To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease
- As an adjunct to diet alone or in combination with other low density lipoprotein cholesterol (LDL-C)- lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C
- As an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C

Repatha® (evolocumab) is FDA approved for:

- In adults with established cardiovascular disease to reduce the risk of myocardial infarction, stroke, and coronary revascularization
- As an adjunct to diet, alone or in combination with other LDL-C-lowering therapies in adults with primary hyperlipidemia, including HeFH, to reduce LDL-C
- As an adjunct to other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C
- As an adjunct to diet and other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with HoFH, to reduce LDL-C

Initial Evaluation

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i. ONE of the following:

A. BOTH of the following:

1. ONE of the following:

a. The patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) AND ONE of the following:

i. Genetic confirmation of one mutant allele at the LDLR, Apo-B, PCSK9, or 1/LDLRAP1 gene **OR**

ii. History of LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) (pretreatment) **OR**

iii. The patient has clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthoma, or xanthelasma) **OR**

iv. The patient has “definite” or “possible” familial hypercholesterolemia as defined by the Simon Broome criteria **OR**

v. The Patient has a Dutch Lipid Clinic Network Criteria score of greater than 5 **OR**

vi. The patient has a treated low-

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equal to 100 mg/dL after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy **OR**

b. The patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) AND ONE of the following:

i. Genetic confirmation of TWO mutant alleles at the LDLR, Apo-B, PCSK9, or LDLRAP1 gene **OR**

ii. History of untreated LDL-C greater than 500 mg/dL (greater than 13 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (greater than or equal to 7.76 mmol/L) **OR**

iii. The patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma) **OR**

c. The patient has a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) AND has ONE of the following:

i. Acute coronary syndrome

ii. History of myocardial infarction

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iv. Coronary or other arterial revascularization

v. History of stroke

vi. History of transient ischemic attack

vii. Peripheral arterial disease, including aortic aneurysm, presumed to be of atherosclerotic origin **OR**

d. The patient has a diagnosis of primary hyperlipidemia **AND** ONE of the following:

i. The patient has a coronary artery calcium or calcification (CAC) score greater than or equal to 300 Agatston units **OR**

ii. The patient has an LDL-C level greater than or equal to 220 mg/dL (greater than or equal to 5.7 mmol/L) while receiving maximally tolerated statin and ezetimibe therapy **OR**

e. The patient has greater than or equal to 20% 10-year ASCVD risk AND ONE of the following:

i. The patient has greater than or equal to 40% 10-year

a) LDL-C greater than or equal to 70 mg/dL while on maximally tolerated statin therapy
AND

b) ONE of the following:

a) The patient has extensive or active burden of ASCVD (i.e., polyvascular ASCVD, which affects all 3 vascular beds — coronary, cerebrovascular, and peripheral arterial; clinical peripheral arterial disease in addition to coronary and/or

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clinical ASCVD event with multivessel coronary artery disease defined as greater than or equal to 40% stenosis in greater than or equal to 2 large vessels; or recurrent myocardial infarction within 2 years of the initial event) in the presence of adverse or poorly controlled cardiometabolic risk factors

OR

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risk elevations in cardiometabolic factors with less-extensive ASCVD (i.e., diabetes, LDL-C greater than or equal to 100 mg/dL, less than high–intensity statin therapy, chronic kidney disease, poorly controlled hypertension, high-sensitivity C-reactive protein greater than 3 mg/L, or metabolic syndrome, usually occurring with other extremely

high-risk characteristics), usually with other adverse or poorly controlled cardiometabolic risk factors present
OR

c) Patients with ASCVD and LDL-C greater than or equal to 220 mg/dL with greater than or equal to 45% 10-year ASCVD risk despite statin therapy
OR

ii. The patient has 30-39% 10-year

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a) LDL-C greater than or equal to 100 mg/dL while on maximally tolerated statin therapy
AND

b) Less-extensive clinical ASCVD (i.e., no polyvascular ASCVD, no clinical peripheral arterial disease, a prior ASCVD event greater than or equal to 2 years prior, and no coronary artery bypass grafting)
AND

c) Adverse or poorly controlled cardiometabolic risk factor(s) including age 65 years or older, current smoking, chronic kidney disease,

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37 nmol/L, high-sensitivity C-reactive protein 1–3 mg/L, metabolic syndrome with a history of myocardial infarction, ischemic stroke, or symptomatic peripheral arterial disease, usually in the presence of other adverse or poorly controlled cardiometabolic risk factors **OR**

iii. The patient has 20-29% 10-year ASCVD risk AND BOTH of the following:

a) LDL-C greater than or equal to 130 mg/dL while on maximally tolerated statins **AND**

b) ONE of the following:

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less extensive ASCVD and well-controlled cardiometabolic risk factors (i.e., no diabetes, nonsmoker, on high-intensity statin with LDL-C less than 100 mg/dL, blood pressure less than 140/90 mm Hg, and C-reactive protein less than 1 mg/dL)

OR

b) The use is for primary prevention with LDL-C greater than

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mg/dL AND BOTH of the following:

i. No clinical ASCVD or CAC less than 100 Agatston units **AND**

ii. Poorly controlled cardiometabolic risk factor **AND**

2. ONE of the following:

a. The patient has been adherent to high-intensity statin therapy (i.e., rosuvastatin greater than or equal to 20 mg daily, atorvastatin greater than or equal to 40 mg daily) for greater than or equal to 8 continuous weeks AND ONE of the following:

i. The patient's LDL-C level after this treatment regimen remains greater than or equal to 70 mg/dL **OR**

C from baseline after this treatment regimen **OR**

iii. If the patient has ASCVD, and ONE of the following:

a) The patient's non HDL-C level after this treatment regimen remains greater than or equal to 100 mg/dL **OR**

b) The patient is at very high risk and the patient's LDL-C level after this treatment regimen remains greater than or equal to 55 mg/dL **OR**

b. The patient has been determined to be statin intolerant by meeting one of the following criteria:

i. The patient experienced statin-related rhabdomyolysis **OR**

ii. The patient experienced skeletal-

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weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and BOTH of the following:

a) The skeletal-related muscle symptoms (e.g., myopathy or myalgia) occurred while receiving separate trials of both atorvastatin AND rosuvastatin (as single-entity or as combination products) **AND**

b) When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the skeletal-related muscle symptoms (e.g., myopathy, myalgia)

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of each respective statin therapy (atorvastatin AND rosuvastatin) **OR**

iii. The patient experienced elevations in hepatic transaminase while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) **OR**

c. The patient has a hypersensitivity to atorvastatin AND rosuvastatin **OR**

d. The patient has an FDA labeled contraindication to atorvastatin AND rosuvastatin **OR**

B. The patient has another FDA approved indication for the requested agent and route of administration **OR**

C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**

II. If the patient has an FDA labeled indication, ONE of the following:

A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

B. The prescriber has provided information in support of using the requested agent for the

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iii. The patient will NOT be using the requested agent in combination with another PCSK9 agent for the requested indication **AND**

VI. The patient does NOT have an FDA approved contraindication to the requested agent **AND**

VII. ONE of the following:

A. The request is for a preferred agent **OR**

B. The patient has tried and had an inadequate response to the preferred agent **OR**

C. The patient has an intolerance or hypersensitivity to the preferred agent **OR**

D. The patient has an FDA labeled contraindication to ALL preferred agents

Length of Approval: 12 months

Renewal Evaluation

Renewal of Target Agent(s) may be considered **medically necessary** when

I. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**

II. The patient has had clinical benefit with the requested agent **AND**

III. The patient has been adherent to requested agent **AND**

IV. If the patient has cardiovascular disease OR hyperlipidemia, then ONE of the following:

A. The patient is currently adherent to high-intensity statin therapy (i.e., rosuvastatin greater than or equal to 20 mg daily, atorvastatin greater than or equal to 40 mg daily) **OR**

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1. The patient experienced statin-related rhabdomyolysis **OR**

2. The patient experienced skeletal-related muscle symptoms (e.g., myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and BOTH of the following:

    a. The skeletal-related muscle symptoms (e.g., myopathy or myalgia) occurred while receiving separate trials of both atorvastatin AND rosuvastatin (as single-entity or as combination products) **AND**

    b. When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the skeletal-related muscle symptoms (e.g., myopathy, myalgia) resolved upon discontinuation of each respective statin therapy (atorvastatin AND rosuvastatin) **OR**

3. The patient experienced elevations in hepatic transaminase while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) **OR**

C. The patient has a hypersensitivity to atorvastatin AND rosuvastatin **OR**

D. The patient has an FDA labeled contraindication to atorvastatin AND rosuvastatin **AND**

V. The patient will NOT be using the requested agent in combination with another

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labeled contraindications to the requested agent

Length of Approval: 12 months

Dates

Original Effective
09-02-2015
Last Review
11-06-2024
Next Review
11-12-2025

CLINICAL RATIONALE

Criteria have been developed to aid in diagnosing HeFH. These include the Simon Broome Register crit and Dutch Lipid clinic Network criteria. (5) Definitive diagnosis of HeFH according to Simon Broome diagnostic criteria requires the patient has one of the following:(3,5)

- Total cholesterol greater than 6.7 mmol/L or low-density lipoprotein cholesterol (LDL-C) greater th 4.0 mmol/L in a child aged younger than 16 years, or greater than 7.5 mmol/L or LDL-C greater t 4.9 mmol/L in an adult (levels either pre-treatment or highest on treatment) **plus** tendon xanthor in the patient, or in first-degree relative (parent, sibling or child), or in second-degree relative (e. grandparent, uncle or aunt) **OR**
- DNA-based evidence of an LDL receptor mutation, familial defective Apo B-100, or a PCSK9 mutat

Possible diagnosis of HeFH according to Simon Broome diagnostic criteria requires the patient has:(3)

- Total cholesterol greater than 6.7 mmol/L or low-density lipoprotein cholesterol (LDL-C) greater th 4.0 mmol/L in a child aged younger than 16 years, or greater than 7.5 mmol/L or LDL-C greater t 4.9 mmol/L in an adult (levels either pre-treatment or highest on treatment)
  AND at least one of the following:
- Family history of myocardial infarction: aged younger than 50 years in second-degree relative or aged younger than 60 years in first-degree relative **OR**
- Family history of raised total cholesterol: greater than 7.5 mmol/L in adult first- or second-degree relative or greater than 6.7 mmol/L in child, brother or sister aged younger than 16 years

The Dutch Lipid Clinic Network criteria assign points based on cholesterol levels, family history hyperlipidemia or cardiovascular disease, clinical presentation, and/or presence of identified genetic mutation affecting plasma LDL-C. (5-7) A definitive diagnosis of HeFH can be made in patients with greater than 8 points. A probable diagnosis can be made in patients with 6-8 poi

Dutch Lipid Clinic Network criteria for diagnosis of heterozygous familial hypercholesterolemia(8)

Group 1: Family history	**Points**

percentile by age and gender for country	1
• First-degree relative with tendon xanthoma and/or corneal arcus	2
• Children less than 18 years with LDL cholesterol greater than 95th percentile by age and gender for country	2
Group 2: Clinical history	**Points**
• Subject has premature (less than 55 years, men; less than 60 years, women) CHD	2
• Subject has premature (less than 55 years, men; less than 60 years, women) cerebral or peripheral vascular disease	1
Group 3: Physical examination	**Points**
• Tendon xanthoma	6
• Corneal arcus in a person less than 45 years	4
Group 4: Biochemical results (LDL-C)	**Points**
• greater than 8.5 mmol/L (greater than 325 mg/dL)	8
• 6.5–8.4 mmol/L (251–325 mg/dL)	5
• 5.0–6.4 mmol/L (191–250 mg/dL)	3
• 4.0–4.9 mmol/L (155–190 mg/dL)	1
Group 5: Molecular genetic testing (DNA analysis)	**Points**
• Causative mutation shown in the LDLR, APOB, or PCSK9 genes	8

Use and Interpretation

Assign only one score, the highest applicable, per group then add the points from each group to achieve the total score

Definitive FH diagnosis: greater than 8 points

Probable FH diagnosis: 6 to 8 points

Possible FH diagnosis: 3 to 5 points

Unlikely FH diagnosis: 0 to 2 points

Guidelines advise that diagnosis of HoFH can be made based on genetic or clinical criteria. Genetic confirmation of the HoFH includes confirmation of two mutant alleles at the LDL-R, APOB, PCSK9, or LDLRAP1 genes.(4,6) While genetic testing may provide a definitive diagnosis of HoFH, it is recognized that in some patients, genetic confirmation remains elusive, despite exhaustive investigation; indeed, the existence of additional FH genes cannot be excluded. Historically, HoFH has been most commonly

parents.(4,6)

According the American Heart Association (AHA), initial treatment for FH should include a high intensit statin.(9) If the LDL-C is not at goal after 3 months of therapy with the high intensity statin and the patient has been adherent, AHA recommends the addition of ezetimibe. For patients who do not respo to this two drug regimen within 3 months, AHA recommends addition of a PCKS9, a bile acid sequestra or niacin. Patients with HoFH who require additional therapy despite treatment with the three drug regimen, AHA recommends addition of Juxtapid and LDL apheresis.(9)

The AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline lists the following as clinical ASCVD:

- Acute coronary syndrome (ACS)
- Myocardial infarction (MI)
- Stable or unstable angina or coronary or other arterial revascularization
- Stroke
- Transient ischemic attack (TIA) or peripheral artery disease (PAD) including aortic aneurysm

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The AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Manageme of Blood Cholesterol states the following regarding PCSK9 therapy(9)

- Severe hypercholesterolemia (LDL-C greater than or equal to 190 mg/dL [greater than or equal to 4.9 mmol/L])
    - In patients 30-75 years of age with heterozygous FH and with an LDL-C level of 100 mg/dL (greater than or equal to 2.6 mmol/L) or higher while taking maximally tolerated statin and ezetimibe therapy, the addition of a PCSK9 inhibitor may be considered
    - In patients 40-75 years of age with a baseline LDL-C level of 220 mg/dL (greater than or equal to 5.7 mmol/L) or higher while receiving maximally tolerated statin and ezetimibe therapy, the addition of a PCSK9 inhibitor may be considered

The AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol states the following regarding PCSK9 therapy:(9)

- Secondary atherosclerotic cardiovascular disease (ASCVD) prevention
    - In patients with clinical ASCVD who are judged to be very high risk and considered for PCSK9 inhibitor therapy, maximally tolerated LDL-C lowering therapy should include maximally tolerated statin therapy and ezetimibe
    - In patients with clinical ASCVD who are judged to be very high risk and who are on maximally tolerated LDL-C lowering therapy with LDL-C 70 mg/dL (greater than or equal to 1.8 mmol/L) or higher or a non-HDL-C level of 100 mg/dL (greater than or equal to 2.6 mmol/L) or higher, it is reasonable to add PCSK9 inhibitor following a clinical-patient discussion about the net benefit, safety, and cost

The AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline categorizes the following statin intensities:(9)

Lowering	equal to 50%		
Statins	Atorvastatin 40-80 mg Rosuvastatin 20-40 mg	Atorvastatin 10-20 mg Rosuvastatin 5-10 mg Simvastatin 20-40 mg (a) Pravastatin 40-80 mg Lovastatin 40-80 mg Fluvastatin XL 80 mg Fluvastatin 40 mg twice daily Pitavastatin 1-4 mg	Simvastatin 10 mg Pravastatin 10-20 mg Lovastatin 20 mg Fluvastatin 20-40 mg

a - Although simvastatin 80 mg was evaluated in RCTs, initiation of simvastatin 80 mg or titration to 8 mg is not recommended by the FDA because of the risk of myopathy, including rhabdomyolysis

The National Lipid Association (NLA) 2019 consensus statement identifies the following patients, who are already on maximally tolerated statin therapy, as most likely to benefit from PCSK9 therapy.(10)

- Extreme high-risk (greater than or equal to 40% 10-year ASCVD risk on maximally tolerated statin therapy) with LDL-C greater than or equal to 70 mg/dL and either of the following:
    - Extensive or active burden of ASCVD (i.e., polyvascular ASCVD, which affects all 3 vascular beds—coronary, cerebrovascular, and peripheral arterial; clinical peripheral arterial disease in addition to coronary and/or cerebrovascular disease; a clinical ASCVD event with multivessel coronary artery disease defined as greater than or equal to 40% stenosis in greater than or equal to 2 large vessels; or recurrent myocardial infarction within 2 years of the initial event) in the presence of adverse or poorly controlled cardiometabolic risk factors
    - Extremely high-risk elevations in cardiometabolic factors with less-extensive ASCVD (i.e., HeFH, diabetes, LDL-C greater than or equal to 100 mg/dL, less than high–intensity statin therapy, chronic kidney disease, poorly controlled hypertension, high-

with ASCVD and HeFH or severe hypercholesterolemia (SH) LDL-C greater than or equal to 220 mg/dL are an additional group of extremely high–risk patients, with greater than or equal to 45% 10- year ASCVD risk despite statin therapy. Statin-treated HeFH patients with coronary artery calcium (CAC) score greater than 100 Agatston units also have about a 45% 10-year ASCVD risk despite statin therapy

- Very high-risk (30-39% 10-year ASCVD risk on maximally tolerated statin therapy) with LDL-C greater than or equal to 100 mg/dL and the following:
  - Less-extensive clinical ASCVD (i.e., no polyvascular ASCVD, no clinical peripheral arterial disease, a prior ASCVD event greater than or equal to 2 years prior, and no coronary artery bypass grafting)
  - Adverse or poorly controlled cardiometabolic risk factor(s) including age greater than or equal to 65 years, current smoking, chronic kidney disease, lipoprotein(a) greater than or equal to 37 nmol/L, high-sensitivity C-reactive protein 1–3 mg/L, metabolic syndrome with a history of myocardial infarction, ischemic stroke, or symptomatic peripheral arterial disease, usually in the presence of other adverse or poorly controlled cardiometabolic risk factors
- High-risk (20-29% 10-year ASCVD risk on maximally tolerated statin therapy) with LDL-C greater than or equal to 130 mg/dL and either of the following:
  - High-risk patients with ASCVD who have the following:
    - Less-extensive ASCVD
    - Well-controlled cardiometabolic risk factors (i.e., no diabetes, nonsmoker, on high-intensity statin with LDL-C less than 100 mg/dL, blood pressure less than 140/90 mm Hg, and C-reactive protein less than 1 mg/dL)
  - Primary prevention patients with HeFH or SH LDL-C greater than or equal to 220 mg/dL and have the following:
    - No clinical ASCVD or CAC less than 100 Agatston units
    - Poorly controlled cardiometabolic risk factor

CAC Agatston score in non-contrast CT can be used for patient risk classification for coronary heart disease:(11,12)

- 0 CAC = no CAC, very low risk,
- 1-99 CAC = mild CAC, mildly increased risk
- 100 - 299 CAC = moderate CAC, moderately increased risk
- greater than or equal to 300 CAC = moderate to severely increased risk

In their 2022 Expert Consensus Decision, the American College of Cardiology stated that in view of the favorable net clinical benefit of the addition of nonstatin therapies is patients with clinical ASCVD at very high risk on high-intensity statin therapy and lifestyle management and the very low levels of LDL-C achieved in RCTs (randomized clinical trials) of nonstatin therapies, a lower LDL-C threshold of LDL-C less than or equal to 55 mg/dL is recommended. Patients in this group have a history of multiple major ASCVD events (e.g., recent [within the past 12 months] acute coronary syndrome, history of MI other than the recent ACS event listed previously, history of ischemic stroke, and

statin therapy and ezetimibe, and history of congestive heart failure. (13)

Quick Code Search

Use this feature to find out if a procedure and diagnosis code pair will be approved, denied or held for review. Simply put in the procedure code, then the diagnosis code, then click "Add Code Pair". If the codes are listed in this policy, we will help you by showing a dropdown to help you.

Procedure

Please type a procedure code

Enter at least the first 3 characters of the code

Diagnosis

Please type a diagnosis code

Enter at least the first 3 characters of the code

Add

CODES

+ **HCPCS**

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REVISIONS

10-01-2024
Removal of specialist criteria per trade contracts.

12-01-2023
Policy reviewed at Medical Policy Committee meeting on 11/8/2023 – no changes to policy.

06-30-2017
Adding indication of clinical atherosclerotic cardiovascular disease (ASCVD) to policy

01-09-2017
Policy criteria revised