MEDICAL MUTUAL®

Drug Policy

Policy:	**201528**	**Initial Effective Date: 10/19/2015**
Code(s):	**HCPCS C9399, J3490 and J3590**	**Annual Review Date: 11/18/2021**
SUBJECT: **Targeted Drugs:**	**PCSK9 Inhibitors** • **Praluent (alirocumab) injection for subcutaneous use** • **Repatha (evolocumab) injection for subcutaneous use**	**Last Revised Date:11/18/2021**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Praluent and Repatha are fully human monoclonal antibodies (mAb) (IgG1 isotype) administered by subcutaneous injection that bind with high affinity and specificity to proprotein convertase subtilisin kexin type 9 (PCSK9) to reduce levels of low-density lipoprotein cholesterol (LDL-C) and other atherogenic lipoproteins.

POLICY STATEMENT

This policy involves the use of PCSK9 Inhibitors (Praluent and Repatha). Prior authorization is recommended for pharmacy and medical benefit coverage of PCSK9 Inhibitors (Praluent and Repatha). Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. 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 PCSK9 Inhibitors (Praluent and Repatha) as well as the monitoring required for AEs and long-term efficacy, initial approval requires PCSK9 Inhibitors (Praluent and Repatha) 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.

Preferred Product Criteria

Product	Exception
Praluent Authorized Alternative (NDCs start with 72733)	**1.** For the Basic Formulary/High Performance Plus Formulary, approve. **2.** For the National Preferred Formulary, approve.
Praluent Brand (NDCs start with 00024)	**1.** For the Basic Formulary/High Performance Plus Formulary, approve if the patient has tried Repatha and Praluent Authorized Alternative (NDCs start with 72733). **2.** For the National Preferred Formulary, approve.

Repatha Authorized Alternative (NDCs start with 72511)	**1.** For the Basic Formulary/High Performance Plus Formulary, approve. **2.** For the National Preferred Formulary, approve.
Repatha Brand (NDCs start with 55513)	**1.** For the Basic Formulary/High Performance Plus Formulary, no longer available. **3.** For the National Preferred Formulary, no longer available.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of PCSK9 Inhibitors (Praluent and Repatha) is recommended in those who meet the following criteria:

1. Heterozygous Familial Hypercholesterolemia (HeFH)

Criteria. *Patient must meet the following criteria (A, B, C, D, E, and F):*

A) The patient meets one of the following (i or ii):
- **i.** For Praluent requests, the patient is aged ≥ 18 years; OR
- **ii.** For Repatha requests, the patient is aged ≥ 10 years; AND

B) Diagnosis of "definite" HeFH. The patient meets the following criteria (i and ii):
- **i.** The patient has an LDL-C level ≥ 190 mg/dL (after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy such as Praluent or Repatha) [documentation required]; AND
- **ii.** The patient meets at least one of the following criteria (a, b, or c) [documentation required]:
  - **a.** The patient has clinical manifestations of HeFH (e.g. tendon xanthomas, cutaneous xanthomas, arcus cornea, tuberous xanthomas or xanthelasma); OR
  - **b.** DNA-based evidence of an LDL-receptor (LDLR) mutation, familial defective apo B-100, a PCSK9 mutation, or an LDL-receptor adaptor protein 1 (LDLRAP1) gene mutation; OR
  - **c.** The prescriber used the Simon Broome criteria and the patient met the threshold for "definite" familial hypercholesterolemia; AND

C) The patient meets one of the following criteria (i or ii):
- **i.** The 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 3 or more continuous months [documentation required]; AND patient was adherent with therapy [documentation required]; AND the LDL-C level remains ≥ 100 mg/dL [documentation required]; OR
- **ii.** The patient has been determined to be statin intolerant by meeting one of the following criteria (a or b):
  - **a.** The patient experienced statin-related rhabdomyolysis (statin-induced muscle breakdown with signs and symptoms such as muscle pain, weakness, tenderness, an elevated creatine kinase [CK] levels [e.g., ≥ 10 times the upper limit of normal], and/or myoglobinuria [myoglobin present in urine]) [documentation required]; OR
  - **b.** The patient experienced skeletal-related muscle symptoms (e.g., myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and meets both of the following criteria [(1) and (2)]:
    - **(1)** 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) [documentation required]; AND
    - **(2)** 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) [documentation required]; AND

D) Used in combination with appropriate diet [documentation required]; AND

E) If able to tolerate statins, the patient continues to receive the maximum tolerated dose of a statin while receiving PCSK9 Inhibitor therapy; AND

F) Prescribed by, or in consultation with, a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders

* **2021 High Performance Plus Formulary –** When prior approval criteria are met but the patient has not tried the preferred product, offer to review for preferred product (Praluent Authorized Alternative).

** **2021 Basic Formulary –** When prior approval criteria are met but the patient has not tried the preferred product, offer to review for preferred product (Praluent Authorized Alternative).

2. Hyperlipidemia in Patients with Clinical Atherosclerotic Cardiovascular Disease (ASCVD)

Criteria. *Approve if the patient meets the following criteria (A, B, C, D, E, and F):*

A) The patient is aged ≥ 18 years; AND

B) The patient meets the following criteria (i and ii):

- **i.** The patient has an LDL-C level ≥ 70 mg/dL (after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy such as Praluent or Repatha) [documentation required]; AND
- **ii.** The patient has had one of the following conditions or diagnoses (a, b, c, d, or e) [documentation required]:
  - **a.** The patient has had a previous myocardial infarction (MI) or has a history of an acute coronary syndrome (ACS); OR
  - **b.** The patient has a diagnosis of angina (stable or unstable); OR
  - **c.** The patient has a past history of stroke or transient ischemic attack (TIA); OR
  - **d.** The patient has peripheral arterial disease (PAD); OR
  - **e.** The patient has coronary artery disease (CAD); OR
  - **f.** The patient has undergone a coronary or other arterial revascularization procedure in the past (e.g. coronary artery bypass graft [CABG], percutaneous coronary intervention [PCI]); AND

C) The patient meets one of the following criteria (i or ii):

- **i.** The 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 3 or more continuous months [documentation required]; AND patient was adherent with therapy [documentation required]; AND the LDL-C level remains ≥ 70 mg/dL [documentation required]; OR
- **ii.** The patient has been determined to be statin intolerant by meeting one of the following criteria (a or b):
  - **a.** The patient experienced statin-related rhabdomyolysis (statin-induced muscle breakdown with signs and symptoms such as muscle pain, weakness, tenderness, an elevated creatine kinase [CK] levels [e.g., ≥ 10 times the upper limit of normal], and/or myoglobinuria [myoglobin present in urine]) [documentation required]; OR
  - **b.** The patient experienced skeletal-related muscle symptoms (e.g., myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and meets both of the following criteria [(1) and (2)]:

(1) 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) [documentation required]; AND

(2) 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) [documentation required]; AND

D) Used in combination with appropriate diet [documentation required]; AND

E) If able to tolerate statins, the patient continues to receive the maximum tolerated dose of a statin while receiving PCSK9 Inhibitor therapy; AND

F) Prescribed by, or in consultation with, a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders.

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** **2021 Basic Formulary –** When prior approval criteria are met but the patient has not tried the preferred product, offer to review for preferred product (Praluent Authorized Alternative).

3. Homozygous Familial Hypercholesterolemia [HoFH]

Criteria. *Patient must meet the following criteria (A, B, C, D, E, F, and G):*

A) The patient meets one of the following (i or ii):
- a. For Praluent requests, the patient is aged ≥ 18 years; OR
- b. For Repatha requests, the patient is aged ≥ 10 years; AND

B) The patient meets one of the following (i or ii):
- i. The patient has genetic confirmation of two mutant alleles 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 locus [documentation required]; OR
- ii. The patient has an untreated LDL-C level > 500 mg/dL (13 mmol/L); OR treated LDL-C level ≥ 300 mg/dL (7.76 mmol/L) (after treatment with antihyperlipidemic agents but prior to agents such as Repatha or Juxtapid® [lomitapide capsules]) [documentation required] AND the patient has clinical manifestations of HoFH (e.g. cutaneous or tendinous xanthomas, arcus cornea, tuberous xanthomas or xanthelasma) before age of 10 years [documentation required]; AND

C) The patient meets one of the following criteria (i or ii):
- i. The patient has tried one high-intensity statin therapy (i.e., atorvastatin ≥ 40 mg daily; rosuvastatin tablets ≥ 20 mg daily [as a single-entity or as a combination product]) for 3 or more continuous months [documentation required] AND the LDL-C level remains ≥ 70 mg/dL [documentation required]; OR
- ii. The patient has been determined to be statin intolerant by meeting one of the following criteria (a or b):
  - **a.** The patient experienced statin-related rhabdomyolysis (statin-induced muscle breakdown with signs and symptoms such as muscle pain, weakness, tenderness, an elevated creatine kinase [CK] levels [e.g., ≥ 10 times the upper limit of normal], and/or myoglobinuria [myoglobin present in urine]) [documentation required]; OR

b. The patient experienced skeletal-related muscle symptoms (e.g., myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and meets both of the following criteria [(1) and (2)]:

(1) 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) [documentation required]; AND

(2) 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) [documentation required]; AND

D) Used in combination with other LDL-lowering therapies (e.g., statins, ezetimibe (Zetia), LDL apheresis) [documentation required]; AND

E) Used in combination with appropriate diet [documentation required]; AND

F) Prescribed by, or in consultation with, a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders; AND

G) The patient does not have two LDL-receptor negative alleles (little to no residual function) [documentation required].

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4. Primary Hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)

Criteria. *Patient must meet the following criteria (A, B, C, D, and E):*

A) The patient is aged ≥ 18 years or older; AND

B) The patient has an LDL-C level ≥ 130 mg/dL (after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy such as Repatha or Praluent) [documentation required]; AND

C) Used in combination with appropriate diet [documentation required]; AND

D) Prescribed by, or in consultation with, a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders; AND

E) The patient meets one of the following (a or b):

a. The 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 3 or more continuous months [documentation required]; AND patient was adherent with therapy [documentation required]; AND the LDL-C level remains ≥ 130 mg/dL [documentation required]; OR

b. The patient has been determined to be statin intolerant by meeting one of the following criteria (i or ii):

i. The patient experienced statin-related rhabdomyolysis (statin-induced muscle breakdown with signs and symptoms such as muscle pain, weakness, tenderness, and/or myoglobinuria [myoglobin present in urine]) [documentation required]; OR

ii. The patient experienced skeletal-related muscle symptoms (e.g., myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and meets both of the following criteria (1 and 2):

1. 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) [documentation required]; AND
2. 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) [documentation required].

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** **2021 Basic Formulary –** When prior approval criteria are met but the patient has not tried the preferred product, offer to review for preferred product (Praluent Authorized Alternative).

5. Patient has been started on Praluent or Repatha

Criteria. *Approve for an indication or condition addressed as an approval in this document if the patient has seen an LDL-C reduction [documentation required] and is considered by the prescriber to be an appropriate response while being treated with Praluent or Repatha. If patients using Praluent require an increase to the 150 mg dose following initiation of Praluent 75 mg, approve for 3 months.*

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** **2021 Basic Formulary –** When prior approval criteria are met but the patient has not tried the preferred product, offer to review for preferred product (Praluent Authorized Alternative).

Initial Approval/ Extended Approval.
A) *Initial Approval:* 3 months
B) *Extended Approval:* 1 year

Dosing in Praluent *(medical benefit only)*: *Dosing must meet the following:*
The recommended starting dose of Praluent is 75 mg administered subcutaneously once every 2 weeks, since the majority of patients achieve sufficient LDL-C reduction with this dosage. If the LDL-C response is inadequate, the dosage may be increased to the maximum dosage of 150 mg administered every 2 weeks. Measure LDL-C levels within 4 to 8 weeks of initiating or titrating PRALUENT to assess response and adjust the dose, if needed.

Dosing in Repatha (medical benefit only). *Dosing must meet the following:*

Heterozygous Familial Hypercholesterolemia [HeFH]
The recommended subcutaneous dosage of Repatha in patients with HeFH is either 140 mg every 2 weeks OR 420 mg once monthly. When switching dosage regimens, administer the first dose of the new regimen on the next scheduled date of the prior regimen.

Homozygous Familial Hypercholesterolemia [HoFH]
The recommended subcutaneous dosage of Repatha in patients with HoFH is 420 mg once monthly. In patients with HoFH, measure LDL-C levels 4 to 8 weeks after starting Repatha, since response to therapy will depend on the degree of LDL-receptor function.

Note: To administer the 420 mg dose, give 3 Repatha injections consecutively within 30 minutes.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

PCSK9 Inhibitors (Praluent and Repatha) have 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. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Concurrent use of Praluent with Repatha (evolocumab injection for SC use).** Repatha and Praluent should not be used together.

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 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.

Prior approval is required for HCPCS Codes C9399†, J3490†, J3590†, or J9999.

†When *unclassified drugs or biologicals* (C9399), *unclassified drugs* (J3490), *unclassified biologics* (J3590), or *unclassified antineoplastics* (J9999) is determined to be Praluent or Repatha.

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Edits and Denials:

Prior approval: Prior approval is required for Praluent and Repatha **(HCPCS Codes C9399, J3490, J3590 and J9999)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Codes C9399, J3490, J3590, and J9999** will pend with **Remark Code PRR** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

HCPCS Code(s):	
C9399	Unclassified drugs or biologics
J3490	Unclassified drugs
J3590	Unclassified biologics