



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Praluent

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Effective Date: 8/17/2023

Last Review Date: 6/7/2023

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Florida Kids
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### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Praluent under the patient's prescription drug benefit.

### Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-Approved Indications

- Praluent is indicated to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
- Praluent is indicated 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, to reduce LDL-C.
- Praluent is indicated as an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

All other indications are considered experimental/investigational and not medically necessary.

### Applicable Drug List:

Praluent

### Policy/Guideline:

#### Documentation:

Submission of the following information is necessary to initiate the prior authorization review:

- Current LDL-C level for both initial requests and continuation requests. The level must be dated within the six months preceding the authorization request.
- Untreated (before any lipid-lowering therapy) LDL-C level if requesting Praluent to treat primary hyperlipidemia, heterozygous or homozygous familial hypercholesterolemia.
- Chart notes confirming clinical atherosclerotic cardiovascular disease (ASCVD) if requesting Praluent to treat clinical ASCVD (see Appendix A).
- If member has contraindication or intolerance to statins, chart notes confirming the contraindication or intolerance (see Appendices B and C).



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### Criteria for Initial Approval:

Note: Repatha is the preferred agent. Requests for Praluent require that the patient is unable to take Repatha for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

#### A. Clinical atherosclerotic cardiovascular disease (ASCVD)

Authorization of 6 months may be granted for treatment of clinical atherosclerotic cardiovascular disease when both of the following criteria are met:

1. Member has a history of clinical ASCVD (see Appendix A).
2. Member meets at least one of the following criteria:
  - i. Member has a current LDL-C level  $\geq 70$  mg/dL after at least three months of treatment with a high-intensity statin dose in combination with ezetimibe. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
  - ii. Member has a current LDL-C level  $\geq 70$  mg/dL with contraindication or intolerance to statins (see Appendices B and C).

#### B. Primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH)

Authorization of 6 months may be granted for treatment of primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH) when both of the following criteria are met:

1. Member had an untreated (before any lipid-lowering therapy) LDL-C level  $\geq 190$  mg/dL in the absence of a secondary cause.
2. Member meets at least one of the following criteria:
  - i. Member has a current LDL-C level  $\geq 100$  mg/dL after at least three months of treatment with a high-intensity statin dose in combination with ezetimibe. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
  - ii. Member has a current LDL-C level  $\geq 100$  mg/dL with contraindication or intolerance to statins (see Appendices B and C).

#### C. Homozygous familial hypercholesterolemia (HoFH)

Authorization of 6 months may be granted for treatment of homozygous familial hypercholesterolemia when both of the following criteria are met:

1. Member had an untreated (before any lipid-lowering therapy) LDL-C level  $\geq 190$  mg/dL in the absence of a secondary cause.



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2. Member meets at least one of the following criteria:
  - i. Member has a current LDL-C level  $\geq 100$  mg/dL after at least three months of treatment with a high-intensity statin dose in combination with ezetimibe. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
  - ii. Member has a current LDL-C level  $\geq 100$  mg/dL with a contraindication or intolerance to statins (see Appendices B and C).

### Continuation of Therapy:

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in criteria for initial approval who achieve or maintain an LDL-C reduction (e.g., LDL-C is now at goal, robust lowering of LDL-C).

### Appendix:

#### APPENDIX A. Clinical ASCVD

- Acute coronary syndromes
- Myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization procedure (e.g., percutaneous coronary intervention [PCI], coronary artery bypass graft [CABG] surgery)
- Stroke of presumed atherosclerotic origin
- Transient ischemic attack (TIA)
- Non-cardiac peripheral arterial disease (PAD) of presumed atherosclerotic origin (e.g., carotid artery stenosis, lower extremity PAD)
- Obstructive coronary artery disease (defined as fifty percent or greater stenosis on cardiac computed tomography angiogram or catheterization)
- Coronary Artery Calcium (CAC) Score  $\geq 1000$

#### APPENDIX B. Statin-associated muscle symptoms (SAMS) and statin re-challenge

- Score of 7 or higher on the Statin-Associated Muscle Symptom Clinical Index (SAMS-CI)
- Statin-associated elevation in creatine kinase (CK) level  $\geq 10$  times upper limit of normal (ULN)

**NOTE:** Statin re-challenge is NOT required for members who have experienced an elevation of CK level  $\geq 10$  times ULN after receiving lipid-lowering therapy (LLT) with a statin.

#### APPENDIX C. Contraindications to statins

- Active liver disease, including unexplained persistent elevations in hepatic transaminase levels (e.g., alanine transaminase (ALT) level  $\geq 3$  times ULN)
- Pregnancy or planned pregnancy



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- Breastfeeding

### Approval Duration and Quantity Restrictions:

#### Approval:

- Initials: 6 months; Renewals: 12 months

#### Quantity Level Limit:

- Praluent 75 mg pen: 2 pens per 28 days
- Praluent 150 mg syringe/pen: 2 syringes/pens per 28 days

#### References:

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