Clinical Policy Title:	alirocumab
Policy Number:	RxA.454
Drug(s) Applied:	Praluent®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Alirocumab (Praluent®) is a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor. It is indicated:

- To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
- As 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
alirocumab (Praluent®)	Primary hyperlipidemia (including HeFH) or hypercholesterolemia with ASCVD	75 mg subcutaneously once every 2 weeks Or 300 mg subcutaneously once every 4 weeks If the LDL-C response is inadequate, dose may be increased to 150 mg once every 2 weeks.	300 mg/month
	HeFH undergoing LDL apheresis or in adults with HoFH	150 mg subcutaneously once every 2 weeks.	300 mg/month

Dosage Forms

- Single-use pre-filled pen, syringe: 75 mg/mL, 150 mg/mL.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the

terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Primary Hyperlipidemia (including HeFH) and Atherosclerotic Cardiovascular Disease (must meet all)**:**

1. Diagnosis of one of the following (a or b):
   a. Primary hyperlipidemia with both of the following (i and ii) (note: these criteria in section I.A.1.a do not apply to HeFH. Refer to section I.A.2 below for coverage criteria for HeFH);
      i. Documentation of one of the following (1 or 2):
         1) Presence of a genetically mediated form of primary hyperlipidemia as evidenced by confirmatory genetic testing results;
         2) A diagnosis of secondary hyperlipidemia has been ruled out with documentation of absence of all of the following potential causes of elevated cholesterol (a-f):
            a) Poor diet;
            b) Hypothyroidism;
            c) Obstructive liver disease;
            d) Renal disease;
            e) Nephrosis;
            f) Medications which can increase lipid levels including, but not limited to: glucocorticoids, sex hormones, antipsychotics, antiretrovirals, immunosuppressive agents, retinoic acid derivatives;
      ii. Baseline LDL-C (prior to any lipid-lowering pharmacologic therapy) was one of the following (1 or 2):
         1) ≥ 190 mg/dL for genetically mediated primary hyperlipidemias;
         2) ≥ 220 mg/dL for non-genetically mediated primary hyperlipidemias;
   b. Atherosclerotic cardiovascular disease (ASCVD) as evidenced by a history of any one of the following conditions (i-vii):
      i. Acute coronary syndromes;
      ii. Clinically significant coronary heart disease (CHD) diagnosed by invasive or non-invasive testing (such as coronary angiography, stress test using treadmill, stress echocardiography, or nuclear imaging);
      iii. Coronary or other arterial revascularization;
      iv. Myocardial infarction;
      v. Peripheral arterial disease presumed to be of atherosclerotic origin;
      vi. Stable or unstable angina;
      vii. Stroke or transient ischemic attack (TIA);
2. For members with HeFH, both of the following are met (a and b):
   a. Baseline LDL-C (prior to any lipid-lowering pharmacologic therapy) was ≥ 190 mg/dL;
   b. HeFH diagnosis is confirmed by one of the following (i or ii):
      i. World Health Organization (WHO)/Dutch Lipid Network familial hypercholesterolemia diagnostic criteria score of > 8 as determined by requesting provider (see Appendix D);
      ii. Definite diagnosis per Simon Broome criteria (see Appendix D);
3. Member does not have a diagnosis of homozygous familial hypercholesterolemia (HoFH);
4. Prescribed by or in consultation with a cardiologist, endocrinologist or lipid specialist;
5. Age ≥ 18 years;
6. For members on statin therapy, both of the following (a and b):
   a. Praluent® is prescribed in conjunction with a statin at the maximally tolerated dose;

b. Member has been adherent for at least the last 4 months to maximally tolerated doses of one of the following statin regimens (i, ii, or iii):
   i. A high intensity statin (see Appendix E);
   ii. A moderate intensity statin (see Appendix E) and member has one of the following (a or b):
      a) Intolerance to two high intensity statins;
      b) A statin risk factor (see Appendix G);
   iii. A low intensity statin and member has one of the following (a or b):
      a) Intolerance to two high and two moderate intensity statins;
      b) A statin risk factor (see Appendix G) and history of intolerance to two moderate intensity statins;

7. For members not on statin therapy, member meets one of the following (a or b):
   a. Statin therapy is contraindicated per Appendix F;
   b. For members who are statin intolerant, member has tried at least four statins, two of which must be hydrophilic statins (pravastatin, fluvastatin, or rosuvastatin), and member meets one of the following (i or ii):
      i. Member has documented statin risk factors (see Appendix G);
      ii. Member is statin intolerant due to statin-associated muscle symptoms (SAMS) and meets both of the following (a and b):
         a) Documentation of intolerable SAMS persisting at least two weeks, which disappeared with discontinuing the statin therapy and recurred with a statin re-challenge;
         b) Documentation of re-challenge with titration from lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly);
8. Member has been adherent to ezetimibe therapy used concomitantly with a statin at the maximally tolerated dose for at least the last 4 months, unless contraindicated per Appendix F or member has a history of ezetimibe intolerance (e.g., associated diarrhea or upper respiratory tract infection);
9. Documentation of recent (within the last 30 days) LDL-C of one of the following (a, b, or c):
   a. ≥ 70 mg/dL for ASCVD;
   b. ≥ 100 mg/dL for genetically mediated severe primary hyperlipidemia (including HeFH);
   c. ≥ 130 mg/dL for non-genetically mediated severe primary hypercholesterolemia;
10. Treatment plan does not include coadministration with Juxtapid® Repatha®;
11. Dose does not exceed 75 mg every 2 weeks or 300 mg per month.

Approval Duration
Commercial: 6 months
Medicaid: 3 months

B. Homozygous familial hypercholesterolemia (HoFH) (must meet all):
1. A diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by ONE of the following:
   a. Presence of a genetically mediated form of primary hyperlipidemia as evidenced by confirmatory genetic testing results;
   b. Untreated LDL-C >500 mg/dL (>13 mmol/L) or treated LDL-C ≥300 mg/dL (≥7.76 mmol/L) with ONE of the following (i or ii):
      i. The patient had cutaneous or tendon xanthoma before age 10 years or;
      ii. Untreated LDL-C levels consistent with HeFH in both parents [untreated LDL-C >190 mg/dL (>4.9 mmol/L)]
2. Prescribed by or in consultation with a cardiologist, endocrinologist or lipidologist;;

3. Age ≥ 18 years;
4. For members on statin therapy, both of the following (a and b):
   a. Praluent® is prescribed in conjunction with a statin at the maximally tolerated dose;
   b. Member has been adherent for at least the last 4 months to maximally tolerated doses of one of the following statin regimens (i, ii, or iii):
      i. A high intensity statin (see Appendix E);
      ii. A moderate intensity statin (see Appendix E) and member has one of the following (a or b):
         a) Intolerance to two high intensity statins;
         b) A statin risk factor (see Appendix G);
      iii. A low intensity statin and member has one of the following (a or b):
         a) Intolerance to two high and two moderate intensity statins;
         b) A statin risk factor (see Appendix G) and history of intolerance to two moderate intensity statins;
5. For members not on statin therapy, member meets one of the following (a or b):
   a. Statin therapy is contraindicated per Appendix F;
   b. For members who are statin intolerant, member has tried at least four statins, two of which must be hydrophilic statins (pravastatin, fluvastatin, or rosuvastatin), and member meets one of the following (i or ii):
      i. Member has documented statin risk factors (see Appendix G);
      ii. Member is statin intolerant due to statin-associated muscle symptoms (SAMS) and meets both of the following (a and b):
         a) Documentation of intolerable SAMS persisting at least two weeks, which disappeared with discontinuing the statin therapy and recurred with a statin re-challenge;
         b) Documentation of re-challenge with titration from lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly);
6. Member has been adherent to ezetimibe and lomitapide therapy used concomitantly with a statin at the maximally tolerated dose for at least the last 3 months, unless contraindicated per Appendix F;
7. Treatment plan does not include coadministration with Juxtapid®, Repatha®;
8. Dose does not exceed 150 mg subcutaneously once every 2 weeks

Approval Duration
Commercial: 6 months
Medicaid: 3 months

II. Continued Therapy Approval

A. All indications in section I (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to the therapy;
3. If statin tolerant, documentation of adherence to a statin at the maximally tolerated dose;
4. Member meets one of the following (a or b):
   a. Request is for 75 mg every 2 weeks or 300 mg every month and lab results within the last 12 months are submitted showing an LDL-C reduction since initiation of Praluent® therapy;
   b. Request is for 150 mg every 2 weeks and one of the following (i or ii):
      i. If request represents a new dose increase, member has demonstrated adherence to Praluent® and, if applicable, ezetimibe and/or statin therapies and lab results within the

last 12 months are submitted showing an LDL-C > 70 mg/dL after a minimum of 8 weeks of Praluent® therapy at 75 mg;

ii. If request represents a continuation of Praluent® 150 mg, lab results within the last 12 months are submitted showing an LDL-C reduction since initiation of the Praluent® dose increase.

Approval DurationCommercial: 6 months
Medicaid: 12 months (3 months if request is for dose increase)

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

ALT: Alanine transaminase
apo B: apolipoprotein B
ASCVD: atherosclerotic cardiovascular disease
CHD: coronary heart disease
FDA: Food and Drug Administration
FH: familial hypercholesterolemia
HeFH: heterozygous familial hypercholesterolemia
HoFH: homozygous familial hypercholesterolemia
LDL-C: low density lipoprotein cholesterol
LDLR: low density lipoprotein receptor
PCSK9: proprotein convertase subtilisin kexin 9
SAMS: statin-associated muscle symptoms
TIA: transient ischemic attack
WHO: World Health Organization

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ezetimibe/simvastatin (Vytorin®)	10/40 mg orally once daily in the evening	10 mg-40 mg/day (Use of the 10/80 mg dose is restricted to patients who have been taking simvastatin 80 mg for 12 months or more without evidence of muscle toxicity)
ezetimibe (Zetia®)	10 mg orally once daily	10 mg/day
atorvastatin (Lipitor®)	40 mg orally once daily	80 mg/day
rosuvastatin (Crestor®)	5 to 40 mg orally once daily	40 mg/day

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - History of serious hypersensitivity reaction to alirocumab or any of the excipients in Praluent®.

- Boxed Warning(s):
  - None reported.

- **APPENDIX D: Criteria for Diagnosis of HeFH**Dutch Lipid Clinic Network criteria for Familial Hypercholesterolemia (FH)

FH Criteria		Points	Member's Score†
Family History			
First-degree relative with known premature* coronary and vascular disease		1	Place highest score here (0, 1 or 2)
First-degree relative with known LDL-C level above the 95th percentile		1	
First-degree relative with tendinous xanthomata and/or arcus cornealis		2	
Children aged < 18 years with LDL-C level above the 95th percentile		2	
Clinical History			
Patient with premature* coronary artery disease		2	Place highest score here (0, 1 or 2)
Patient with premature* cerebral or peripheral vascular disease		1	
Physical Examination			
Tendinous xanthomata		6	Place highest score here (0, 4 or 6)
Arcus cornealis prior to age 45 years		4	
Cholesterol Levels - mg/dL (mmol/liter)			
LDL-C ≥ 330 mg/dL ≥ 8.5)		8	Place highest score here (0, 1, 3, 5 or 8)
LDL-C 250 – 329 mg/dL (6.5 – 8.4)		5	
LDL-C 190 – 249 mg/dL (5.0 – 6.4)		3	
LDL-C 155 – 189 mg/dL (4.0 – 4.9)		1	
DNA Analysis			
Functional mutation in the low-density lipoprotein receptor (LDLR), apo B or PCSK9 gene		8	Place highest score here (0 or 8)

TOTAL SCORE	Definite FH: >8	Place score total here __

Premature – men < 55 years or women < 60 years

†Choose the highest score from each of the five categories and then add together for a total score. The five categories are 1) Family History, 2) Clinical History, 3) Physical Examination, 4) Cholesterol Levels, and 5) DNA Analysis.

- Simon Broome Register Group Definition of Definite FH (meets 1 and 2):
  1. One of the following (a or b):
     a. Total cholesterol level above 7.5 mmol/l (290 mg/dl) in adults or a total cholesterol level above 6.7 mmol/l (260 mg/dl) for children under 16
     b. LDL levels above 4.9 mmol/l (190 mg/dl) in adults (4.0 mmol/l in children) (either pre-treatment or highest on treatment)
  2. One of the following (a or b):
     a. Tendinous xanthomas in patient or relative (parent, child, sibling, grandparent, aunt, uncle)
     b. DNA-based evidence of an LDL receptor mutation or familial defective apo B100.

- High and Moderate Risk of ASCVD:
  - Patients with high risk of ASCVD include the following:
    - History of clinical atherosclerotic cardiovascular disease (as defined in section II)
    - Diabetes with an estimated 10-year ASCVD risk ≥ 7.5% for adults 40-75 years of age
    - Untreated LDL ≥ 190 mg/dL
    - Patients with moderate risk of ASCVD include the following:
    - Diabetes with an estimated 10-year ASCVD risk < 7.5% for adults 40-75 years of age
    - Estimated 10-year ASCVD risk ≥ 5% for adults 40-75 years of age
    - The calculator for the 10-year ASCVD risk estimator can be found here: http://tools.cardiosource.org/ASCVD-Risk-Estimator/. Information needed to complete the ASCVD Risk Estimator include: gender, race (white, African American, other), systolic blood pressure, diabetes, age, total cholesterol, HDL-Cholesterol, treatment for hypertension, current smoker.

APPENDIX E: High and Moderate Intensity Daily Statin Therapy for Adults:

High Intensity Statin Therapy ***Daily dose shown to lower LDL-C, on average, by approximately ⩾ 50%***
• atorvastatin 40-80 mg • rosuvastatin 20-40 mg
Moderate Intensity Statin Therapy ***Daily dose shown to lower LDL-C, on average, by approximately 30% to 50%***
• atorvastatin 10-20mg • fluvastatin xl 80 mg • fluvastatin 40 mg 2x/day • lovastatin 40 mg
High Intensity Statin Therapy DL ***Daily dose shown to lower LDL-C, on average, by approximately ≥ 50%***

- pitavastatin 2-4 mg
- pravastatin 40-80 mg
- rosuvastatin 5-10 mg
- simvastatin 20-40 mg

Low Intensity Statin Therapy
Daily dose shown to lower LDL-C, on average, by <30%

- simvastatin 10 mg
- pravastatin 10–20 mg
- lovastatin 20 mg
- fluvastatin 20–40 mg
- pitavastatin 1 mg

APPENDIX F: Statin, Ezetimibe, and Lomitapide contraindications:

Statins

- Decompensated liver disease (development of jaundice, ascites, variceal bleeding, encephalopathy).
- Laboratory-confirmed acute liver injury or rhabdomyolysis resulting from statin treatment.
- Pregnancy, actively trying to become pregnant, or nursing.
- Immune-mediated hypersensitivity to the HMG-CoA reductase inhibitor drug class (statins) as evidenced by an allergic reaction occurring with at least TWO different statins.

Ezetimibe

- Moderate or severe hepatic impairment [Child-Pugh classes B and C]
- Hypersensitivity to ezetimibe (e.g., anaphylaxis, angioedema, rash, urticaria)

Lomitapide

- Moderate or severe hepatic impairment or active liver disease including unexplained persistent abnormal liver function tests
- Pregnancy
- Concomitant use with strong or moderate CYP3A4 inhibitors.

APPENDIX G: Statin Risk Factors:

Statin Risk Factors

- Multiple or serious comorbidities, including impaired renal or hepatic function
- Unexplained alanine transaminase (ALT) elevations > 3 times upper limit of normal, or active liver disease
- Concomitant use of drugs adversely affecting statin metabolism
- Age > 75 years, or history of hemorrhagic stroke
- Asian ancestry

APPENDIX H: General Information

- FDA Endocrinologic and Metabolic Drugs Advisory Committee briefing documents for Praluent® discuss the questionable determination of statin intolerance, stating: “many patients who are not able to take statins are not truly intolerant of the pharmacological class.”

- Patients should remain on concomitant therapy with a statin if tolerated due to the established long-term cardiovascular benefits.
- Examples of genetically mediated primary hyperlipidemia include but are not limited to the following:
  - Familial hypercholesterolemia
  - Familial combined hyperlipidemia (FCHL)
  - Polygenic hypercholesterolemia
  - Familial dysbetalipoproteinemia
- The diagnosis of SAMS is often on the basis of clinical criteria. Typical SAMS include muscle pain and aching (myalgia), cramps, and weakness. Symptoms are usually bilateral and involve large muscle groups, including the thigh, buttock, back, and shoulder girdle musculature. In contrast, cramping is usually unilateral and may involve small muscles of the hands and feet. Symptoms may be more frequent in physically active patients. Symptoms often appear early after starting stain therapy or after an increase in dose and usually resolve or start to dissipate within weeks after cessation of therapy, although it may take several months for symptoms to totally resolve. Persistence of symptoms for more than 2 months after drug cessation should prompt a search for other causes or for underlying muscle disease possibly provoked by statin therapy. The reappearance of symptoms with statin rechallenge and their disappearance with drug cessation offers the best evidence that the symptoms are truly SAMS.
- Pravastatin, fluvastatin, and rosuvastatin are hydrophilic statins which have been reported to confer fewer adverse drug reactions than lipophilic statins.

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Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1) Policy title table was updated. 2) Line of Business Policy Applies to was update to all lines of business. 3) Initial and Continued Therapy Approval criteria: Commercial approval duration was updated from “6 months or to the member’s renewal date, whichever is longer **“**to “6 months”. 4) Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 5) Continued Approval criteria II.A.3 “lab results within the past 3 months” was updated to “lab results within the past 12 months”. 6) Updated Appendix B: added “once daily in the evening” for brand Vytorin. 7) References were updated.	07/29/2020	09/14/2020
Policy was reviewed: 1) Background was updated to include new indication Homozygous familial hypercholesterolemia (HoFH), “As an adjunct to other LDL-C-lowering therapies…”. 2) Dosing Information dosing regimen was updated to include new indication, “…or in adults with HoFH”. . 3) Statement about provider sample ‘‘The	07/07/2021	09/14/2021

provision of provider samples does not guarantee coverage…" was added to Clinical Policy . 4) Initial Approval Criteria I.B was updated to include a new indication, "Homozygous familial hypercholesterolemia (HoFH)". 5) Continued Therapy Approval Criteria II.A was updated from "Primary Hyperlipidaemia (including HeFH) and Atherosclerotic Cardiovascular Disease" to "All Indications in Section I." 6) Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 7) Continued Therapy ApprovalCriteria II.A.2 was updated to include "Member is responding positively to the therapy;". 8) Initial approval Crtieria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 9) Therapeutic Alternatives verbiage was updated to "Below are suggested therapeutic alternatives based on clinical guidance..". 10) Statement about drug listing format in Appendix B is updated to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 11) Appendix C contraindication was updated from "History of serious hypersensitivity reaction to Praluent" to "History of serious hypersensitivity reaction to alirocumab or any of the excipients in Praluent." 12) Appendix F table was updated to include drug name Lomitapide and its respective contraindications. 13) References were reviewed and updated.		