

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Praluent (alirocumab)

Override(s)	Approval Duration
Prior Authorization	Initial Authorization Duration: 6 months
Quantity Limit	Continued Authorization Duration: 12 months

Medications	Quantity Limit
Praluent (alirocumab)	2 injections (2 mL) per 28 days

APPROVAL CRITERIA

Initial requests for Praluent (alirocumab) may be approved when the following criteria are met:

- I. Individual has had an adequate trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and titration of Repatha and achieved suboptimal lipid lowering response, despite at least 90 days of compliant therapy;

AND

- II. Individual is at high risk atherosclerotic cardiovascular disease (ASCVD) events as identified by one of the following:
 - A. Individual has Homozygous Familial Hypercholesterolemia (HoFH) confirmed by (Cuchel 2014, Singh 2015):
 1. Presence of two mutant alleles at the LDLR, apolipoprotein B (apoB), PCSK9 or ARH adaptor protein (LDLRAP1) gene locus; **OR**
 2. One of the following:
 - a. An untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L); **OR**
 - b. Treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) **AND** one of the following:
 - i. Cutaneous or tendonous xanthoma before age of 10 years; **OR**
 - ii. Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than 190 mg/dL);

OR

- B. Individual has Heterozygous Familial Hypercholesterolemia (HeFH) confirmed by (Singh 2015, WHO 1999):

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1. Presence of a mutation in LDLR, apolipoprotein B (apoB), PCSK9 or ARH adaptor protein gene (LDLRAP1) gene; **OR**
2. World Health Organization (WHO)/Dutch Lipid Network Criteria with score of greater than 8 points;

OR

C. Individual has a history of clinical atherosclerotic cardiovascular disease (ASCVD), including **one or more** of the following (ACC 2016):

1. Acute coronary syndromes;
2. Coronary artery disease (CAD);
3. History of myocardial infarction (MI);
4. Stable or unstable angina;
5. Coronary or other arterial revascularization;
6. Stroke;
7. Transient ischemic attack (TIA);
8. Peripheral arterial disease (PAD);

AND

III. Individual meets **one** of the following:

- A. Individual is on high intensity statin therapy, or statin therapy at the maximum tolerated dose (high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher) (ACC 2016, AACE 2017); **OR**
- B. Individual is statin intolerant based on one of the following:
 1. Inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, demonstrated by intolerable symptoms or clinically significant biomarker changes (NLA 2014); **OR**
 2. Statin associated rhabdomyolysis after a trial of one statin;

OR

C. Individual has a contraindication for statin therapy including active liver disease, unexplained persistent elevation of hepatic transaminases, or pregnancy;

AND

IV. Individual is on ezetimibe in addition to statin therapy (only applies to individuals on statin therapy) (ACC 2016);

AND

V. Individual, excluding HoFH, has achieved suboptimal lipid lowering response, despite at least 90 days of compliant lipid lowering therapy and lifestyle modifications as defined (ACC 2016):

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- A. For individuals where initial LDL-C is known:
 - 1. Less than 50% reduction LDL-C;
- B. For individuals where initial LDL-C is unknown:
 - 1. ASCVD and LDL-C remains greater than or equal to 70mg/dL; **OR**
 - 2. No history of ASCVD and LDL-C remains greater than or equal to 100mg/dL;

Continuation requests for Praluent (alirocumab) may be approved when the following criteria are met:

- I. Individual continues to receive concomitant maximally tolerated statin therapy (unless contraindication or individual is statin intolerant); **AND**
- II. Confirmation of LDL reduction has been provided.

Praluent (alirocumab) may **not** be approved for the following:

- I. Concurrent use with Juxtapid (lomitapide) or Kynamro (mipomersen).

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
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- DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 20, 2018.
- DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- Guyton JR, Bays HE, Grundy SM, Jacobson TA. The National Lipid Association Statin Intolerance Panel. An assessment by the Statin Intolerance Panel: 2014 update. *J Clin Lipidol*. 2014;8(3 Suppl):S72–81.
- Jellinger PS, Handelsman Y, Rosenblit PD, et al. American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for management of dyslipidemia and prevention of cardiovascular disease. *Endocr Pract*. 2017;23(Suppl 2):1-87.

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7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
8. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol.* 2016;68:92–125.
9. Singh S, Bittner V. Familial hypercholesterolemia--epidemiology, diagnosis, and screening. *Curr Atheroscler Rep.* 2015; 17(2):482.
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CRX-ALL-0320-19