Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Praluent (alirocumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial Authorization Duration: 6 months 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 than190 mg/dL);

   OR

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

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

C. Individual has a history of clinical atherosclerotic cardiovascular disease (ASCVD), including **one or more** of the following (AHA/ACC 2018):
   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 a 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) (AHA/ACC 2018, 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) (AHA/ACC 2018);

AND

V. Individual, excluding HoFH, has achieved suboptimal lipid lowering response, despite at least 90 days of compliant lipid lowering therapy and lifestyle modificationsas defined (AHA/ACC 2018):
   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:

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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. All other indications not included above; **OR**
II. Concurrent use with Juxtapid (lomitapide) or Kynamro (mipomersen).

Key References:

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2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 11, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Grundy SM, Stone NJ, Bailey AL, et. al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol. *J Am Coll Cardiol.* 2018. https://doi.org/10.1016/j.jacc.2018.11.003.
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7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
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9. World Health Organization. Familial hypercholesterolemia—report of a second WHO Consultation. Geneva, Switzerland: World Health Organization, 1999. Available at: http://whqlibdoc.who.int/hq/1999/WHO_HGN_FH_CONS_99.2.pdf?ua=1. Accessed: July 11, 2019.