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

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Praluent (alirocumab)

DRUG.00078

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

Requests for **initiation therapy** of Praluent (alirocumab) may be approved if 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 18 years of age or older and is at high risk for Acute Coronary Syndrome (ACS) as identified by one of the following:
   A. Homozygous Familial Hypercholesterolemia (HoFH) confirmed by:
      1. Presence of two mutant alleles at the LDLR, apoB, PCSK9 or ARH adaptor gene locus; **OR**
      2. An untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L) or 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. Heterozygous Familial Hypercholesterolemia (HeFH) confirmed by:
      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;

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

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OR

C. History of Clinical Atherosclerotic Cardiovascular Disease (ASCVD), including one or more of the following:
   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** or more of the following:
   A. Individual is a on high intensity statin therapy, or statin therapy at the maximum tolerated dose, where high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher; **OR**
   B. Individual is statin intolerant, as defined by the National Lipid Association Statin Intolerance Panel and includes all of the following:
      1. Inability to tolerate at least two statins, with at least one started at the lowest starting daily dose; **AND**
      2. Statin dose reduction is attempted for symptom and biomarker abnormality resolution, rather than discontinuation of statin therapy altogether; **AND**
      3. Intolerable symptoms or abnormal biomarker changes are reversible upon statin discontinuation, but reproducible by re-challenge of statins, if clinically appropriate. Statin re-challenge may be appropriate for individuals with all of the following:
         i. Symptomatic; **AND**
         ii. Creatine kinase is less than four times the upper limit of normal per laboratory reference range; **AND**
         iii. AST/ALT are less than three times the upper limit of normal per laboratory reference range;

      AND

      4. Symptoms or biomarker abnormalities are not attributable to established predispositions or conditions recognized to increase the risk of statin intolerance, such as:
         i. Hypothyroidism;
         ii. Drug interactions;
         iii. Concurrent illness;

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

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iv. Significant changes in physical activity/exercise;
v. Underlying muscle disease;

OR

C. Individual has a condition that is a contraindication for statin therapy including active liver disease, unexplained persistent elevation of serum transaminases, or pregnancy, which does not exist for Praluent;

AND

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

AND

V. High risk individual has achieved suboptimal lipid lowering response, despite at least 90 days of compliant lipid lowering therapy and lifestyle modifications, where suboptimal response is defined:
   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. There is confirmation of CVD and LDL-C remains greater than or equal to 70mg/dl; **OR**
      2. No documented history of CVD and LDL-C remains greater than or equal to 100mg/dl;

Requests for **continuation of therapy** of Praluent (alirocumab) may be approved if the following criteria are met:

I. Criteria listed above have been met; **AND**
II. There is confirmation of LDL reduction.

Praluent (alirocumab) may **not** be approved when used concurrently with Juxtapid (lomitapide) or Kynamro (mipomersen).

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

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

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

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