ALIROCUMAB

Generic	Brand	HICL	GCN	Exception/Other
ALIROCUMAB	PRALUENT PEN, PRALUENT SYRINGE	42347		

***********Customer Service/PAC Alert************
(For Internal Use Only)

THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT SUBMITTING FOR PHARMACIST REVIEW.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
   - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

   If yes, continue to #3.
   If no, continue to #4.

3. Will the patient continue statin treatment as described above in combination with Praluent?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
   - The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have an LDL-cholesterol level greater than or equal to 70 mg/dL?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has **ONE** of the following diagnoses:
     - Established cardiovascular disease (e.g., history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis)
     - Primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)) as determined by meeting **ONE** of the following:
       - Simon Broome diagnostic criteria (definite)
       - Dutch Lipid Network criteria with a score of at least 6

   If yes, **approve for 12 months by HICL with a quantity limit of #2mL (2 syringes/pens) per 28 days.**
   If no, do not approve
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **ALIROCUMAB (Praluent)** requires a diagnosis of established cardiovascular disease (e.g., history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis) **OR** primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)). The following criteria must also be met:

- The patient is 18 years of age or older
- The agent is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
- The patient has an LDL-cholesterol level greater than or equal to 70 mg/dL

For statin tolerant patients, approval also requires:

- The patient meets **ONE** of the following criteria:
  - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
  - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
- The patient will continue statin treatment in combination with Praluent

For statin intolerant patients, approval also requires ONE of the following:

- The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
- The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

For patients with primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)), approval also requires the diagnosis is determined by meeting **ONE** of the following:

- Simon Broome diagnostic criteria (definite)
- Dutch Lipid Network criteria with a score of at least 6

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GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of established cardiovascular disease **OR** primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)) **AND** meet **ONE** of the following criteria?
   - The patient has continued concurrent therapy with a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   - The patient has continued concurrent therapy with a maximally tolerated dose of any statin
   - The patient has an absolute contraindication to statin therapy
   - The patient has complete statin intolerance

   If yes, **approve for 12 months by HICL with a quantity limit of #2mL (2 syringes/pens) per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **ALIROCUMAB (Praluent)** requires a diagnosis of established cardiovascular disease or primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)). In addition, **ONE** of the following must be met:
   - The patient has continued concurrent therapy with a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   - The patient has continued concurrent therapy with a maximally tolerated dose of any statin
   - The patient has an absolute contraindication to statin therapy
   - The patient has complete statin intolerance

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Praluent.

REFERENCES

- Praluent [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis US LLC; April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/19
Created: 08/15
Client Approval: 06/19
P&T Approval: 07/19