Gateway HealthSM
Non-Formulary Prior Authorization Criteria

PCSK9 Inhibitors

Coverage is provided in the following situations:

- The prescribed medication is age appropriate based upon FDA-approved labeling
- The medication is being prescribed by a qualified specialist or there is documentation the PCSK9 inhibitor is being prescribed in consultation with a qualified specialist (cardiologist, endocrinologist, lipid specialist)
- Documentation of adherence or counseling to lipid-lowering lifestyle interventions, including exercise and a low fat, low cholesterol diet
- Documentation of lipid panel results at baseline (pre-treatment), current LDL level with treatment (within the month) and goal LDL level are provided
- The dose and frequency requested is within FDA-approved labeling (dose optimization) and consistent with quantity limits
- The member will not be taking the requested PCSK9 inhibitor concurrently with another PCSK9 inhibitor or with Juxtapid (lomitapide) or Kynamro (mipomersen)[HoFH only]
- The member will be obtaining the medication from a qualified network specialty pharmacy
- All requests deemed medically necessary and approved will be referred to care management for review for assistance with disease state management, non-pharmacologic therapy, help with treatment of other modifiable risk factors to help decrease the risk of heart disease and other psychosocial issues

Certain criteria for each diagnosis must be met in order for approval to be granted:

- For the treatment of heterozygous familial hypercholesterolemia (HeFH)\textsuperscript{1,2,3,4}:
  - Documentation of HeFH confirmed as “definite” by a score of > 8 using the Dutch Lipid Clinic Network criteria (all points added to calculate the total score must be documented) OR confirmed as “definite” by the Simon-Broome criteria. Clinical evidence and laboratory results must be provided to support the diagnosis
  - The member will be taking a PCSK9 inhibitor concurrently with a maximally tolerated statin as indicated per the FDA approved indication along with a low fat, low-cholesterol diet
  - Pertaining to the member’s current lipid-lowering treatment regimen:
    - The member has had an adequate trial of at least two statins at the maximally tolerated dose AND the member has been adherent to statin therapy as evidenced by consistent pharmacy claims over the past 6 months unless the member is new to the plan. If new to plan, documentation from prescribing physician and/or patient’s pharmacy demonstrates adherence to therapy over the past 6 months
    - Documented therapeutic failure, intolerance, or contraindication to Zetia (available through the exceptions review process) in combination with statin therapy
    - Documentation, within the past month, that the member’s LDL-C is >100 mg/dL (without ASCVD) or >70 mg/dL (with ASCVD) while adherent to a maximally

\textsuperscript{1}\textsuperscript{2}\textsuperscript{3}\textsuperscript{4}
tolerated dose of statin therapy alone and in combination with other lipid lowering therapy (Zetia and bile acid sequestrant or niacin)

- **For the treatment of Clinical Atherosclerotic Cardiovascular Disease (ASCVD) requiring additional lowering of LDL-cholesterol:**
  - Documentation of a diagnosis of clinical atherosclerotic cardiovascular disease\(^5,6\) defined as one of the following:
    - Acute Coronary Syndrome
    - History of Myocardial Infarction
    - Stable or unstable Angina
    - Coronary revascularization
    - Other arterial revascularization
    - Stroke
    - Transient Ischemic Attack
    - Peripheral Arterial Disease
  
  **AND**
  - The member will be taking a PCSK9 inhibitor concurrently with a maximally tolerated statin
  
  **AND**
  - Pertaining to the member’s current lipid-lowering treatment regimen:
    - The member has had an adequate trial of at least two statins at the maximally tolerated dose **AND** the member has been adherent to statin therapy as evidenced by consistent pharmacy claims over the past 6 months, unless new to the plan. If new to plan, documentation from prescribing physician and/or patient’s pharmacy demonstrates adherence to therapy over the past 6 months
    
    **AND**
    - Documented therapeutic failure, intolerance, or contraindication to Zetia (ezetimibe), approved through the exceptions review process, in combination with statin therapy\(^7\)
    
    **AND**
    - Documentation, within the past month, that the member’s LDL-C is > 70 mg/dL while adherent to a maximally tolerated dose of statin therapy alone and in combination with Zetia (ezetimibe)

- **For the treatment of homozygous familial hypercholesterolemia (HoFH)-Repatha (evolocumab) only \(^1,2,3,4\):**
  - Documented diagnosis of HoFH (clinical documentation and laboratory results must be provided to support the diagnosis) confirmed by:
    - An untreated LDL-C >500 mg/dL or a treated LDL-C ≥ 300 mg/dL with at least **one** of the following:
      - Presence of cutaneous or tendon xanthoma before 10 years of age
      - Both parents have documented elevated LDL-C before lipid-lowering treatment (pre-treatment) consistent with a diagnosis of heterozygous familial hypercholesterolemia [e.g. untreated LDL-C >190 mg/dL]
    
    **OR**
    - Previous history of genetic confirmation of two mutant alleles in the LDLR, Apo-B, PCSK9, or LDLRAP1 gene locus
  
  **AND**
  - The member will be taking Repatha concurrently with other lipid lowering therapies as indicated in the FDA approved labeling
Updated 12/19/2016
PARP Approved 1/30/2017

AND
- Repatha will not be used concomitantly with Juxtapid (lomitapide) or Kynamro (mipomersen)

AND
- Pertaining to the member’s current lipid-lowering treatment regimen:
  - The member has had an adequate trial of at least two statins at the maximally tolerated dose AND the member has been adherent to statin therapy as evidenced by consistent pharmacy claims over the past 6 months, unless new to the plan. If new to plan, documentation from prescribing physician and/or patient’s pharmacy demonstrates adherence to therapy over the past 6 months
  AND
  - Documented therapeutic failure, intolerance, or contraindication to Zetia (ezetimibe), approved through the exceptions review process, in combination with statin therapy
  AND
  - Documentation, within the past month, that the member’s LDL-C is > 100 mg/dL (without ASCVD) or >70 mg/dL (with ASCVD) while adherent to lipid lowering therapies

Length of approval: three (3) months

Reauthorization Criteria
- The member is adherent to PCSK9 inhibitor therapy as evidenced by consistent pharmacy claims
- Documentation the member is adherent to statin treatment in combination with Praluent or Repatha. For a diagnosis of HoFH, documentation the member is adherent to lipid lowering therapies (e.g. statins, ezetimibe) in combination with Repatha
- The medication is being prescribed by an appropriate qualified specialist or documentation a PCSK9 inhibitor is being prescribed in consultation with a qualified specialist (cardiologist, endocrinologist, lipid specialist)
- The dose requested is within FDA-approved labeling and frequency of administration, in alignment with the package insert (dose optimization) and consistent with quantity limits
- For a dose increase whether the prescriber submits supporting documentation such as peer reviewed medical literature supporting the dose increase in order to achieve LDL-C goal specified at initial request
- LDL-C drawn after treatment initiation with a PCSK9 inhibitor demonstrates improvement while on maximized therapy

Length of approval: six (6) months

When criteria are not met, the requested will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

References:


