Hyperlipidemia Agents
PA criteria—standardized formatting

PCSK9 Inhibitors

Praluent and Repatha are both formulary options. Repatha has a QL restricting use to 140mg q 2weeks. Approval of Repatha 420mg monthly requires trial of Praluent dosed every two weeks (exceptions made for members with homozygous familial hyperlipidemia).

New Start Criteria

1. Is member being treated for an OHP funded condition?
    a. Yes; move to question 2
    b. No; Deny category 1: Not a covered benefit

2. Does member have a diagnosis of homozygous or heterozygous familial hypercholesterolemia?
    a. Yes; move to question 4
    b. No; Move to question 3

3. Does the member have a diagnosis of clinical atherosclerotic cardiovascular disease substantiated by hospital admission, imaging study or surgical procedure:
    - History of myocardial infarction or other acute coronary syndrome
    - Coronary or other revascularization procedure
    - Transient ischemic attack or ischemic stroke
    - Atherosclerotic peripheral arterial disease
    - Coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis
    - Carotid plaque with 50% or more stenosis
    a. Yes; Move to question 4
    b. No; Deny category 3: Not a covered benefit

4. Is the member over the age of 18? *Exceptions for pediatric members over the age of 13 with a diagnosis of homozygous familial hyperlipidemia--Repatha only.*
    a. Yes; Move to question 5
    b. No; Deny category 3: Not a covered benefit

5. Is the medication being prescribed by, or in consultation with a cardiologist, endocrinologist or lipid specialist?
    a. Yes; Move to question 6
    b. No; Deny category 5: Not medically appropriate.

6. Submitted documentation shows member is a non-smoker or is actively quitting smoking.
    a. Yes; Move to question 7
    b. No; Deny category 5: Not medically appropriate

7. Member with less than 50% reduction in LDL-C after 12 months of therapy with:
    - High Intensity Statin + ezetimibe

- Low to Moderate intensity statin if intolerant of high intensity statin + ezetimibe (must include documentation demonstrating inability to tolerate high intensity statin)
- Ezetimibe AND another LDL lowering agent (bile acid sequestrant, fibrate or niacin), due to failing at least 3 statin agents (must meet statin intolerance criteria)*

a. Yes; Move to question 8
b. No; Deny category 5: Not medically appropriate

8. Has member been 80% or greater adherent to maximal drug treatment?
    a. Yes; Move to question 9.
    b. No; Deny category 5: Not medically appropriate.

9. Will PCSK9 inhibitor agent be used in conjunction with maximal LDL lowering therapy?
    a. Yes; Move to question 10
    b. No; Deny category 5: Not medically appropriate

10. Is requested PCSK9 agent formulary? Or has member tried and failed formulary options within the QL?
    a. Yes; Approve for 12 week trial.
    b. No; Deny category 5: Not medically appropriate

Renewal Criteria

1. Does member show 80% or greater adherence to concurrent statin therapy, ezetimibe and PCSK9 inhibitor therapy?
    a. Yes; Move to question 2
    b. No; Deny category 5: Not medically appropriate

2. Since initiation of PCSK9 therapy does member show a response of:
    a. 40% or greater LDL reduction for diagnosis of atherosclerotic cardiovascular disease
    b. 35% or greater LDL reduction for heterozygous familial hypercholesterolemia
    c. 20% or greater LDL reduction for homozygous familial hypercholesterolemia
    a. Yes; Move to question 3
    b. No; Deny category 5: Not medically appropriate

3. Member maintains recommended behavior modifications
    - Currently a non-smoker or actively quitting smoking
    a. Yes; Approve for 12 months
    b. No; Deny category 5: Not medically appropriate

Zetia Prior Authorization Criteria

New Start Criteria

1. Is member being treated for an OHP funded condition?
   a. Yes: Move to question #2
   b. No: Deny category 1: Not a covered benefit

2. Is the member being treated for any of the following?
   - Homozygous familial hypercholesterolemia
   - Homozygous sitosterolemia
   - Primary hyperlipidemia

   a. Yes: Move to question #3
   b. No; Deny category 3: Not a covered benefit

3. Has member failed therapy on maximally titrated dose of high intensity statins: atorvastatin and Crestor?
   a. Yes; Move to question 4
   b. No; Deny category 3: Not a covered benefit

4. Does member show 80% or greater medication adherence to high intensity statin?
   a. Yes; Move to question 5
   b. No: Deny category 5: Not medically appropriate

5. Submitted documentation shows member is a non-smoker or is actively quitting smoking.
   a. Yes; Move to question 6
   b. No; Deny category 5: Not medically appropriate

6. Is medication intended for use with a high intensity statin?
   a. Yes; approve for 12 week trial
   b. No; Move to question 7

7. Does member meet criteria for statin intolerance?
   a. Yes; Approve for 12 week trial
   b. No; Deny category 5: Not medically appropriate

Renewal Criteria

1. Has the member showed 80% or greater adherence to current statin + Zetia regimen?
   Statin adherence will not be evaluated if member approved previously with documented statin intolerance
   a. Yes; move to question 2
   b. No; Deny category 5: Not medically appropriate

2. Has member showed improvement in LDL from baseline? Yes: Approve for 12 months No: Forward to MD for medical appropriateness (Cat 5) evaluation
   a. Yes; Approve for 12 months
   b. No; Deny category 5: Not medically appropriate

Hyperlipidemia Agents
PA criteria—standardized formatting

Statin Intolerance Criteria for Hyperlipidemia authorization requests

1. Has the member experienced persistent myalgia or myopathy on 2 separate trials (at least a 3 month trial) of moderate- or high-intensity statins separated by an adequate washout period (2-4 weeks) in the last 12 months–AND-
2. The member failed rechallenge with a third statin agent, including a low-intensity statin and/or alternate dosing strategies such as every-other-day statin dosing-AND-
3. Severe and intolerable adverse effects occurred with every trial of statin, and other potential causes were ruled out (low vitamin D levels, sudden increase in intense or prolonged physical activity, drug interactions with statins, other metabolic or inflammatory causes)

----------OR----------

4. Documentation of at least ONE of the following lab values or incidents;
    - CK increase above the upper limit of normal during statin therapy
    - LFTs increase above the upper limit of normal during statin therapy
    - Hospitalization due to severe adverse event such as rhabdomyolysis presumed to be due to statin therapy
    - Severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group presumed to be due to statin therapy (e.g. unable to stand from a seated position, etc.)
    - Contraindication to statin therapy (e.g. decompensated liver disease, pregnancy, nursing female, hypersensitivity reaction)