Hyperlipidemia Agents—PA criteria
Reviewed December 1st 2015
WVP Health Authority Pharmacy and Therapeutics Committee

**PCSK9 Inhibitor Approval Criteria**

| **New Start Criteria:** | | |
|---|---|---|
| 1. Is member being treated for an OHP funded condition? | Yes: Move to #2 | No: Category 1 denial |
| 2. Does member have a diagnosis of homozygous or heterozygous familial hypercholesterolemia? | Yes: Move to #4 | No: Move to #3 |
| 3. Does the member have a diagnosis of clinical atherosclerotic cardiovascular disease substantiated by hospital admission, imaging study or surgical procedure:<br>• History of myocardial infarction or other acute coronary syndrome<br>• Coronary or other revascularization procedure<br>• Transient ischemic attack or ischemic stroke<br>• Atherosclerotic peripheral arterial disease<br>• Coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis<br>• Carotid plaque with 50% or more stenosis | Yes: Move to #4 | No: Category 3 denial |
| 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.* | Yes: Move to #5 | No: Category 3 denial |
| 5. Is the medication being prescribed by, or in consultation with a cardiologist, endocrinologist or lipid specialist? | Yes: Move to #6 | No: Forward to MD for medical appropriateness (Cat 5) evaluation |
| 6. Submitted documentation shows member is a non-smoker or is actively quitting smoking. | Yes: Move to #7 | No: Forward to MD for medical appropriateness (Cat 5) evaluation |
| 7. Member with less than 50% reduction in LDL-C after 12 months of therapy with:<br>• High Intensity Statin + ezetimibe<br>• Low to Moderate intensity statin if intolerant of high intensity statin + ezetimibe (must include documentation demonstrating inability to tolerate high intensity statin) | Yes: Move to #8 | No: Forward to MD for medical appropriateness (Cat 5) evaluation |

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| • 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)* | | |
| 8. Has member been 80% or greater adherent to maximal drug treatment? | Yes: Move to #9 | No: Forward to MD for medical appropriateness (Cat 5) evaluation |
| 9. Will PCSK9 inhibitor agent be used in conjunction with maximal LDL lowering therapy? | Yes: Move to #10 | No: Forward to MD for medical appropriateness (Cat 5) evaluation |
| 10. Is requested PCSK9 agent formulary? Or has member tried and failed formulary options within the QL? | Yes: Approve for 12 week trial | No: Forward to MD for medical appropriateness (Cat 5) evaluation |

*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).

| **PCSK9 Inhibitor Renewal Criteria** | | |
|---|---|---|
| 1. Does member show 80% or greater adherence to concurrent statin therapy, ezetimibe and PCSK9 inhibitor therapy? | Yes: Move to #2 | No: Forward to MD for medical appropriateness (Cat 5) evaluation |
| 2. Since initiation of PCSK9 therapy does member show a response of:<br>• 40% or greater LDL reduction for diagnosis of atherosclerotic cardiovascular disease<br>• 35% or greater LDL reduction for heterozygous familial hypercholesterolemia<br>• 20% or greater LDL reduction for homozygous familial hypercholesterolemia | Yes: Move to #3 | No: Forward to MD for medical appropriateness (Cat 5) evaluation |
| 3. Member maintains recommended behavior modifications<br>• Currently a non-smoker or actively quitting smoking | Yes: Approve for 12 months | No: Forward to MD for medical appropriateness (Cat 5) evaluation |

**Zetia Prior Authorization Criteria**

| New Start Criteria | | |
|---|---|---|
| 1. Is member being treated for an OHP funded condition? | Yes: Move to question #2 | No: Category 1 denial |
| 2. Is the member being treated for any of the following? | Yes: Move to question #3 | No: Category 3 denial |

| | | |
|---|---|---|
| • Homozygous familial hypercholesterolemia<br>• Homozygous sitosterolemia<br>• Primary hyperlipidemia | | |
| 3. Has member failed therapy on maximally titrated dose of high intensity statins: atorvastatin and Crestor? | Yes: Move to question #4 | No: Move to question #5 |
| 4. Does member show 80% or greater medication adherence to high intensity statin? | Yes: Move to question #6 | No: Forward to MD for medical appropriateness (Cat 5) evaluation |
| 5. Submitted documentation shows member is a non-smoker or is actively quitting smoking. | Yes: Move to #6 | No: Forward to MD for medical appropriateness (Cat 5) evaluation |
| 6. Is medication intended for use with a high intensity statin? | Yes: Approve for 12 week trial | No: Move to question #7 |
| 7. Does member meet criteria for statin intolerance? | Yes: Approve for 12 week trial | No: Forward to MD for medical appropriateness (Cat 5) evaluation |
| Renewal Criteria | | |
| 1. Has the member showed 80% or greater adherence to current statin + Zetia regimen?<br>*Statin adherence will not be evaluated if member approved previously with documented statin intolerance* | Yes: Move to question #2 | No: Forward to MD for medical appropriateness (Cat 5) evaluation |
| 2. Has member showed improvement in LDL from baseline? | Yes: Approve for 12 months | No: Forward to MD for medical appropriateness (Cat 5) evaluation |

| ***Statin Intolerance criteria** |
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| 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-<br>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-<br>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)<br>----------OR----------<br>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)

**Statin Intensity Table**

| High-Intensity Statin (HIS) | Moderate-Intensity Statin (MIS) | Low-Intensity Statin (LIS) |
|---|---|---|
| Daily dose lowers LDL-C on average, approximately ≥50% | Daily dose lowers LDL-C on average, approximately 30% to <50% | Daily dose lowers LDL-C on average <30% |
| **Atorvastatin 40mg – 80mg**<br>Rosuvastatin 20mg – 40mg | **Atorvastatin 10mg – 20mg**<br>Rosuvastatin 5mg – 10mg<br>**Simvastatin 20mg – 40mg**<br>**Pravastatin 40mg – 80mg**<br>Lovastatin 40mg<br>Fluvastatin XL 80mg<br>Fluvastatin 40mg BID<br>Pitavastatin 2-4mg | **Simvastatin 10mg**<br>**Pravastatin 10-20mg**<br>Lovastatin 20mg<br>Fluvastatin 20-40mg<br>Pitavastatin 1mg |

| Guide to Denial Categories | Reason for Denial |
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| Category 1 | The condition is not on a funded line |
| Category 3 | The use of the medication is considered experimental/ investigational (usually applies to off-label use of a medication) |
| Category 5 | Not medically appropriate |
| Category 15 | Formulary medications have not been exhausted |