

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: <ul style="list-style-type: none"> • 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 	Yes: Move to #4	No: Category 3 denial
4. Is the member over the age of 18? <i>Exceptions for pediatric members over the age of 13 with a diagnosis of homozygous familial hyperlipidemia--Repatha only.</i>	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: <ul style="list-style-type: none"> • 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) 	Yes: Move to #8	No: Forward to MD for medical appropriateness (Cat 5) evaluation

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<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 40% or greater LDL reduction for diagnosis of atherosclerotic cardiovascular disease 35% or greater LDL reduction for heterozygous familial hypercholesterolemia 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 <ul style="list-style-type: none"> Currently a non-smoker or actively quitting smoking 	Yes: Approve for 12 months	No: Forward to MD for medical appropriateness (Cat 5) evaluation

Crestor 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

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<ul style="list-style-type: none"> • Heterozygous familial hypercholesterolemia in pediatric patient • Homozygous familial hypercholesterolemia • Hyperlipidemia and mixed dyslipidemia • Hypertriglyceridemia • Primary dysbetalipoproteinemia • Primary and secondary prevention of ASCVD according to the ACC/AHA Guidelines 		
3. Has member failed therapy on maximally titrated dose of preferred formulary option atorvastatin?	Yes: Move to question #4	No: Forward to MD for medical appropriateness (Cat 5) evaluation
4. Does member show 80% or greater adherence to previously failed statin therapy?	Yes: Approve for 24 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 regimen?	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? <ul style="list-style-type: none"> • Homozygous familial hypercholesterolemia • Homozygous sitosterolemia • Primary hyperlipidemia 	Yes: Move to question #3	No: Category 3 denial
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

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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? <i>Statin adherence will not be evaluated if member approved previously with documented statin intolerance</i>	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
<ol style="list-style-type: none"> 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) <p style="text-align: center;">-----OR-----</p> <ol style="list-style-type: none"> 4. Documentation of at least ONE of the following lab values or incidents; <ul style="list-style-type: none"> • 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)

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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 Rosuvastatin 20mg – 40mg	Atorvastatin 10mg – 20mg Rosuvastatin 5mg – 10mg Simvastatin 20mg – 40mg Pravastatin 40mg – 80mg Lovastatin 40mg Fluvastatin XL 80mg Fluvastatin 40mg BID Pitavastatin 2-4mg	Simvastatin 10mg Pravastatin 10-20mg Lovastatin 20mg Fluvastatin 20-40mg Pitavastatin 1mg

Guide to Denial Categories	Reason for Denial
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