

PCSK9 Inhibitors



Included Products: REPATHA (EVOLOCUMAB), PRALUENT (ALIROCUMAB)

Created:6/21/2017

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Hypercholesterolemia			
Initial Criteria: All Diagnoses		If yes	If no
1.	Is request from a cardiologist, endocrinologist, or lipid specialist?	Continue to #2	Do not approve
2.	Does the member have Homozygous Familial Hypercholesterolemia (HoFH) confirmed with a genetic test?	Approve for lifetime.	Continue to #3.
3.	Does the member have established Atherosclerotic Cardiovascular Disease (ASCVD)?	Continue to #4.	Continue to #7.
4.	<p>Does the member have very high risk ASCVD as evidenced by either: 1) history of multiple major ASCVD events or 2) 1 major ASCVD event AND multiple high-risk conditions</p> <ul style="list-style-type: none"> a. Major ASCVD Events <ul style="list-style-type: none"> i. Recent (past 12 months) acute coronary syndrome (ACS) ii. Prior myocardial infarction (other than recent ACS event listed above) iii. Prior ischemic stroke iv. Symptomatic peripheral arterial disease b. High-Risk Conditions <ul style="list-style-type: none"> i. Age ≥65 years ii. Heterozygous familial hypercholesterolemia (HeFH) iii. Prior coronary revascularization outside of the major ASCVD event(s) iv. Diabetes mellitus v. Hypertension 	Continue to #5.	Continue to #6.

	<ul style="list-style-type: none"> vi. Chronic kidney disease (eGFR 15-59 mL/min/1.73m²) vii. Current smoking viii. LDL-C ≥100 mg/dL despite maximally tolerated statin and ezetimibe ix. History of congestive heart failure 		
5.	<p>Does the member have an LDL greater than or equal to 55 mg/dL despite maximum tolerated dose of high intensity statin (atorvastatin 40-80 mg, rosuvastatin 20-40 mg) + ezetimibe?</p> <ul style="list-style-type: none"> a. Yes, continue to #10. b. If physician states statin associated side effects prevent use of high intensity statin therapy, continue to #9. c. No, do not approve and require alternatives OR state member is at goal. 		
6.	<p>Does the member have an LDL greater than or equal to 70 mg/dL despite maximum tolerated dose of high intensity statin (atorvastatin 40-80 mg, rosuvastatin 20-40 mg) + ezetimibe?</p> <ul style="list-style-type: none"> a. Yes, continue to #10. b. If physician states statin associated side effects prevent use of high intensity statin therapy, continue to #9. c. No, do not approve and require alternatives OR state member is at goal. 		
7.	<p>Does the member have Heterozygous Familial Hypercholesterolemia (HeFH) or baseline LDL greater than or equal to 190 mg/dL?</p>	Continue to #8.	Do not approve. Not guideline recommended.
8.	<p>Does the member have an LDL greater than or equal to 100 mg/dL despite maximum tolerated dose of high intensity statin (atorvastatin 40-80 mg, rosuvastatin 20-40 mg) + ezetimibe?</p> <ul style="list-style-type: none"> a. Yes, continue to #10. b. If physician states statin associated side effects prevent use of high intensity statin therapy, continue to #9. c. No, do not approve and require alternatives OR state member is at goal. 		
9.	<p>Statin Intolerance: Is the patient unable to tolerate high-intensity statin therapy documented by one of the following?</p> <ul style="list-style-type: none"> a. Severe statin-associated side effects (rhabdomyolysis, hepatotoxicity-small 	Continue to #10.	Do not approve.

	<p>increases in transaminases are not considered severe)</p> <p>b. If statin-associated side effects are not severe, has re-challenge with an alternate statin been attempted AND have non-statin causes been addressed?</p> <p>c. Medical contraindication to be on a statin regimen due to non-modifiable factors?</p>		
10.	Approve for 6 months.		
Renewal Criteria		If yes	If no
1.	Is the patient continuing maximum adjunctive treatment (i.e. statin, ezetimibe/BAS, low fat diet, exercise)?	Continue to #2.	Do not approve.
2.	Has the patient been adherent with the medication?	Continue to #3.	Do not approve.
3.	Has there been a significant* LDL reduction while on medication? *Significant lowering of LDL-C is defined as a > 30% decrease in LDL-C.	Continue to #4.	Do not approve.
4.	Approve for lifetime.		

REFERENCES

- Lloyd-Jones DM, Morris PB, Ballantyne CM, Birtcher KK, Covington AM, DePalma SM, Minissian MB, Orringer CE, Smith SC Jr, Waring AA, Wilkins JT. 2022 ACC expert consensus decision pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2022;80: 1366-1418. Reference 2