

6/21/2019

# STANDARDIZED ONE PAGE PHARMACY PRIOR AUTHORIZATION FORM

**Mississippi Division of Medicaid,** Pharmacy Prior Authorization Unit, 550 High St., Suite 1000, Jackson, MS 39201

☐ Medicaid Fee for Service/Change Healthcare
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ttp://www.uhccommunityplan.com/health-professionals/ms/pharmacy-program.html
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ttp://www.molinahealthcare.com/providers/ms/medicaid/pages/home.aspx

BENEFICIARY INFORMATION					
Beneficiary ID: DOB:	/				
Beneficiary Full Name:					
PRESCRIBER INFORMATION					
Prescriber's NPI:					
Prescriber's Full Name:	Phone:				
Prescriber's Address:	FAX:				
PHARMACY INFORMATION					
Pharmacy NPI:					
Pharmacy Name:					
Pharmacy Phone:	Pharmacy FAX:				
CLINICAL INFORMATION					
Requested PA Start Date: Requested PA End Date:					
Drug/Product Requested: Strengt	h: Quantity:				
Days Supply: RX Refills: Diagnosis or ICD-10 Code	(s):				
Hospital Discharge Additional Medical Justification Attached					
Medications received through coupons and/or samples are not acceptable as justification					
PLEASE COMPLETE AND FAX DRUG SPECIFIC CRITERIA/ADDITIONAL DOCUMENTATION FORM FOUND BELOW					
Prescribing provider's signature (signature and date stamps, or the signature of anyone other than the provider, are not acceptable)					
I certify that all information provided is accurate and appropriately documented in the patient's medical chart.					
Signature required:	Date:				
Printed name of prescribing provider:					

## **FAX THIS PAGE**

### PRIOR AUTHORIZATION DESCRIPTION



### Familial Hypercholesterolemia: REPATHA™ (evolocumab) and PRALUENT® (alirocumab)

### Appendix A: Statin Contraindications

- Decompensated liver disease (symptoms can include jaundice, pruritus, ascites, variceal hemorrhage, or hepatic encephalopathy).
- Immune-mediated hypersensitivity to the HMG-CoA reductase inhibitor drug class (statins) as evidenced by an allergic reaction occurring with at least TWO different statins
- Laboratory-confirmed acute liver injury resulting from statin treatment
- Laboratory-confirmed rhabdomyolysis resulting from statin treatment
- Women who are breastfeeding, pregnant or are actively trying to become pregnant

### Appendix B: Zetia Contraindications/Reasons to Discontinue

- Moderate or severe hepatic impairment (CP classes B and C)
- Women who are breastfeeding/pregnant or are actively trying to become pregnant
- Immune-mediated hypersensitivity to the cholesterol absorption as evidenced by an allergic reaction including anaphylaxis, angioedema, rash, or urticaria

## Appendix C: A moderate-intensity statin may be more appropriate for the following adult populations if not able to tolerate a high-intensity statin

- Multiple or serious comorbidities, including impaired renal or hepatic function
- Unexplained ALT elevations >3 times ULN
- Active liver disease
- History of previous statin intolerance or statin-related muscle disorder
- Patient characteristics or concomitant use of drugs affecting statin metabolism
- >75 years of age
- History of hemorrhagic stroke
- Asian ancestry

#### Clinical atherosclerotic cardiovascular disease (ASCVD) includes:

Acute coronary syndromes, or history of myocardial infarction, stable or unstable angina, coronary or
other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease
presumed to be of atherosclerotic origin.

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TABLE 1: Dosage Levels for Statin Therapy Intensity Levels							
Low-Intensity Statin Therapy	Moderate-Intensity Statin Therapy	High-Intensity Statin Therapy					
Daily dose lowers LDL-C by < 30%, on average	Daily dose lowers LDL-C by 30% to 50%, on average	Daily dose lowers LDL-C by ≥ 50%, on average					
• Simvastatin 10 mg	Atorvastatin 10-20 mg	• Atorvastatin 40-80 mg					
<ul> <li>Pravastatin 10-20 mg</li> </ul>	• Rosuvastatin 5-10 mg	• Rosuvastatin 20-40 mg					
<ul> <li>Lovastatin 20 mg</li> </ul>	• Simvastatin 20-40 mg						
<ul> <li>Fluvastatin 20-40 mg</li> </ul>	• Pravastatin 40-80 mg						
<ul> <li>Pitavastatin (Livalo) 1 mg</li> </ul>	• Lovastatin 40 mg						
	• Fluvastatin XL (Lescol XL) 80 mg						
	<ul> <li>Fluvastatin 40 mg twice daily</li> </ul>						
	• Pitavastatin (Livalo) 2-4 mg						

TABLE 2: Dutch Lipid Clinic Network criteria for Familial Hypercholesterolemia	TABLE 2: Dutch Lipid Clinic Network criteria for Familial Hypercholesterolemia			
Criteria	Points			
Family History				
First-degree relative with known premature* coronary and vascular disease, OR	1			
First-degree relative with known LDL-C level above the 95 <sup>th</sup> percentile				
First-degree relative with tendinous xanthomata and/or arcus cornealis, <b>OR</b>	2			
Children aged < 18 years with LDL-C level above the 95th percentile				
Clinical History				
Patient with premature* coronary artery disease	2			
Patient with premature* cerebral or peripheral vascular disease	1			
Physical examination				
Tendinous xanthomata	6			
Arcus cornealis prior to age 45 years	4			
Cholesterol levels mg/dL (mmol/liter)				
LDL-C ≥330 mg/dL (≥8.5)	8			
LDL-C 250 – 329 mg/dL (6.5 – 8.4)	5			
LDL-C 190 – 249 mg/dL (5.0 – 6.4)	3			
LDL-C 155 – 189 mg/dL (4.0 – 4.9)	1			
DNA analysis				
Functional mutation in the LDLR, apo B or PCSK9 gene	8			
Diagnosis (diagnosis is based on total number of points obtained)				
Definite familial hypercholesterolemia	>8			
Probable familial hypercholesterolemia	6-8			
Possible familial hypercholesterolemia	3 – 5			
Unlikely familial hypercholesterolemia	<3			

<sup>\*</sup>Premature – men < 55 years or women < 60 years Apo B= apoliprotein B

LDL-C= low density lipoprotein cholesterol; LDLR=low density lipoprotein receptor FH=familial hypercholesterolemia PCSK9=Proprotein convertase subtilisin/kexin type 9

## CRITERIA/ADDITIONAL DOCUMENTATION

# Heterozygous Familial Hypercholesterolemia WITH ASCVD (HeFH)



BENEFICIARY	NFORMATION						
Beneficiary ID	<u>_</u>	_		DOB:		1	
Deficition y 1D	·			БОВ	<u>/</u>		
Beneficiary Full Name:							
Heterozygou	s Familial Hyperchol	esterolemia (HeFH) wi	th ASC	VD Criteria			
Initial Approval C		IA™ (EVOLOCUMAB) a umab) or Praluent® (alirocum		•	•	itaria are met	
☐ Yes ☐ No	The member is ≥ 18 years		ab) illay i	be approved when the	ie following cri	iteria are met.	
AND	The member is a 10 years	0. 460.					
☐ Yes ☐ No	Repatha™ (evolocumab) or Praluent® (alirocumab) must be prescribed by or in consultation with a cardiologist, endocrinologist or lipid specialist and there is clinical documentation for a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), defined as one of the following: acute coronary syndrome, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin.						
AND							
☐ Yes ☐ No	Unable to meet LDL-C goal after treatment of at least 2 sequential 12-week trials of different high intensity statins [(i.e., atorvastatin ≥40mg or rosuvastatin ≥ Fc20mg] with at least one concomitant 12-week use of Zetia (ezetimibe) 10mg UNLESS contraindicated or not tolerated. (See Appendices A and C). Suboptimal response is defined as where:  • LDL-C is known: <50% reduction in LDL-C from pre-treatment levels						
AND			·				
The member will be using the PCSK9 inhibitor concomitantly with a maximally-tolerated statin unless statin intolerant (See Appendices).  In ASCVD patients with/without comorbidities*, who are on maximally tolerated statin-ezetimibe or non-statin combination therapy in the setting of documented statin intolerance, who achieve a less-than-anticipated response with <50% reduction in LDL-C, it is reasonable to prescribe alirocumab or evolocumab (in addition to or in place of ezetimibe) as second step to achieve further LDL-C reduction.  *Comorbidities defined as: diabetes, recent (<3 month) ASCVD event, ASCVD event while already on statin, poorly controlled risk factors, elevated lipoprotein or chronic kidney disease not on hemodialysis.  If a PCSK9 inhibitor is prescribed, clinicians should continue maximally tolerated statin and monitoring for adherence to medications and lifestyle, side effects, and ongoing LDL-C response to therapy. Adherence to current statin regimen must be evidenced by consistent pharmacy claims over the past 12 weeks, unless new to Medicaid.							
Recommended	Dosing Regimen and Aut	thorization Limit					
	Drug		Dosing	g Regimen			
	Pralue	ent®		g SC Q 2 weeks			
	Repat	ha™	140mg	g SC Q 2 weeks			
Reauthorization	n Criteria:						
☐ Yes ☐ No		Prior Authorization has been	satisfied	,			
AND							
☐ Yes ☐ No							
AND							
☐ Yes ☐ No Documentation of a LDL-C reduction from pretreatment level by ≥ 50% after adding Repatha (evolocumab) or by ≥ 40% after adding Praluent® (alirocumab) for at least 90 days of therapy.							
Authorization							
Initial: If approv	ved, initial coverage will b	e granted for up to 12 wee	ks.				
Maintenance:	Maintenance: If approved, maintenance coverage will be reauthorized for periods of up to 52 weeks.  APPENDICES AND TABLES CAN BE FOUND IN THE INSTRUCTION SHEET						
AFFEINDICES AND TABLES CAN BE FOUND IN THE INSTRUCTION SHEET							

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