Managed Medicaid PCSK9 Inhibitors Prior Authorization Request Form

About

This document contains information about prior authorization criteria for proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors. Approvals will be granted for a period of 6 months. PCSK9 inhibitors are FDA-approved for use with diet and adjunct treatment with maximally-tolerated statin therapy in adults with familial hypercholesterolemia or those with atherosclerotic cardiovascular disease (ASCVD) whose low density lipoprotein cholesterol (LDL-C) is not adequately maintained with the current available treatments. The American Heart Association and American College of Cardiology recommends lifestyle modifications including a healthy diet and physical exercise to improve LDL-C levels.

Treatment Approval Criteria for Praluent (alirocumab)

1. Individual is 18 years of age or older
2. Diagnosis of heterozygous familial hypercholesteremia (HeFH) **OR** diagnosis of ASCVD
3. Concurrent treatment with maximally tolerated doses of atorvastatin or rosuvastatin PLUS ezetimibe
4. Treatment failure with maximally tolerated doses of atorvastatin for 90 days, rosuvastatin* for 90 days **AND** ezetimibe for 90 days. Ezetimibe should be taken in combination with one of the above statins in attempt to achieve the lowest possible LDL-C level prior to requesting PSCK9 inhibitor therapy.
    a. Treatment failure is defined as inability to obtain LDL-C less than or equal to 130 mg/dl after receiving each of these medications for at least 90 days.
    b. Consideration for alternative adjunctive therapies may be given for individuals with documented evidence of a contraindication to atorvastatin and rosuvastatin.

Treatment Approval Criteria for Repatha (evolocumab)

1. Individual is 13 years and older with diagnosis of homozygous familial hypercholesteremia (HoFH)
    OR
2. Individual is 18 years of age and older with diagnosis of heterozygous familial hypercholesteremia **OR** clinical atherosclerotic cardiovascular disease
3. Concurrent treatment with maximally tolerated doses of atorvastatin or rosuvastatin PLUS ezetimibe.
4. Treatment failure with maximally tolerated doses of atorvastatin for 90 days, rosuvastatin* for 90 days **AND** ezetimibe for 90 days. Ezetimibe should be taken in addition to the above statins(s) in attempt to achieve the lowest possible LDL-C level.
    a. Treatment failure is defined as inability to obtain LDL-C less than or equal to 130 mg/dl after receiving each of these medications for at least 90 days.
    b. Consideration for alternative adjunctive therapies may be given for individuals with documented evidence of a contraindication to atorvastatin and rosuvastatin.

Rosuvastatin authorization: *Please refer to the Texas Preferred Drug List (PDL) for the preferred or non-preferred status of products. The PDL requirement for the statin class, "treatment failure with at least two preferred drugs accounting for no less than 120 days of therapy combined", will be overridden for individuals with a documented diagnosis from above, and a statement indicating the pursuance of PCSK9 inhibitor approval, in order to obtain rosuvastatin authorization. Atorvastatin must be used for at least 90 days, prior to receiving a rosuvastatin override.*

Renewal Criteria

1. Patient must maintain concurrent use with maximally tolerated atorvastatin or rosuvastatin therapy.
    - Consideration for alternative adjunctive therapies may be given for individuals with documented evidence of a contraindication to atorvastatin and rosuvastatin
    - Once approved for PCSK9 inhibitor therapy, patients are not required to maintain therapy with ezetimibe.
2. Clinical response to PCSK9 inhibitor therapy must be demonstrated by significant lowering (50% reduction in LDL-C for HeFH and 30% for HoFH) of LDL-C since initiation of PCSK9 inhibitor therapy. Current LDL-C level will be required for renewal approval at 6 months.

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Prescriber Checklist

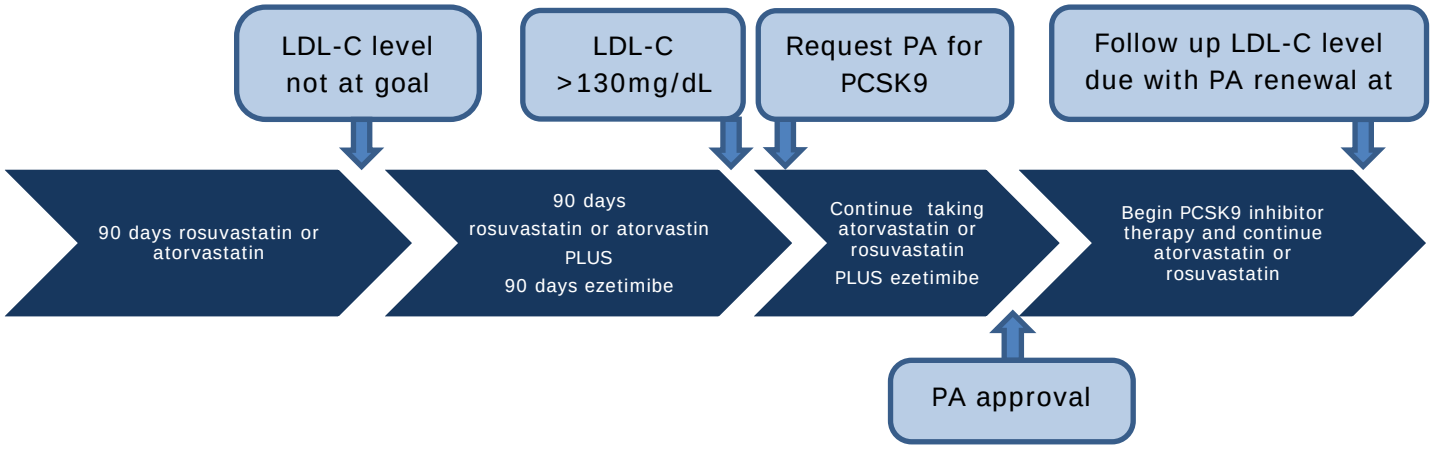
INITIAL APPROVAL REQUIREMENTS

- ☐ 90 days of treatment with atorvastatin
- ☐ 90 days of treatment with rosuvastatin
- ☐ 90 days of treatment with ezetimibe concurrently with atorvastatin or rosuvastatin, immediately prior to PSCK9 inhibitor PA request
- ☐ LDL-C level >130mg/dl despite treatment with 90 days of atorvastatin treatment, 90 days of rosuvastatin, and most recently, 90 days of ezetimibe treatment
- ☐ Client meets minimum age and diagnosis requirements
- ☐ Completed PCSK9 inhibitor prior authorization form

RENEWAL APPROVAL REQUIREMENTS

- ☐ Concurrent therapy with atorvastatin or rosuvastatin, unless evidence of contraindication exists
- ☐ Documented recent LDL-C level demonstrates LDL-C lowering since initiation of PCSK9 inhibitor therapy (50% LDL-C reduction since PCSK9 inhibitor therapy initiation for clients with HeFH, and 30% LDL-C reduction for clients with a diagnosis of HoFH)

TREATMENT TIMELINE EXAMPLE



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Section 1 - Patient Information

First Name	Last Name	MI

DOB	Cardholder ID	Applicable drug allergies

Section 2 - Patient History

Required Diagnosis (please check one of the following):	
☐ Diagnosis of Heterozygous Familial Hypercholesteremia	Date of diagnosis:
☐ Clinical Atherosclerotic Cardiovascular Disease	Date of diagnosis:
☐ Diagnosis of Homozygous Familial Hypercholesteremia	Date of diagnosis:

Drug Treatment History (complete as applicable):

Drug	Last prescribed dose	Start date	End date (if applicable)
☐ atorvastatin			
☐ ezetimibe			
☐ rosuvastatin			
☐ other (list drug name(s) below)			

Section 3 - PCSK9 Inhibitor Prescription Information

Drug name and strength:	Directions:

Please indicate PSCK9 treatment status

☐ Initial	☐ Continuation; Date of treatment initiation: _____

Section 4 - Laboratory Information

LDL-C prior to initiation of PCSK9 treatment: _____ mg/dL	Date level obtained: _____ (for first time requests, level must be from previous 60 days)
Current LDL-C: _____ mg/dL*	Date level obtained: _____ (level must be from previous 60 days)

*Required for renewal requests only. Must have at least a 50% reduction in LDL-C compared to LDL-C level prior to PCSK-9 treatment initiation for patients with HeFH and at least a 30% reduction in LDL-C for patients with HoFH for renewal approval.

Section 5 - Prescriber Information and Signature

Prescriber Name (Last, First)		Prescriber NPI	
Address	City	State	ZIP

Prescriber license	Specialty (if applicable)	Office Phone
Preparer Name (if other than prescriber)		Office Fax

By signing below, I, the prescriber, certify that the information provided above is verifiable and accurate to the best of my knowledge.

Prescriber Signature: **Date:**

Please fax the completed form to Cigna-HealthSpring at 1-888-766-6341
Prescribers with questions regarding this form may call Cigna-HealthSpring at 1-888-671-7379