TEXAS Health and Human Services

Texas Vendor Drug Program

PCSK9 Inhibitors Authorization Request (Medicaid Fee-for-Service)

About

Proprotein convertase subtilisin/kexin type 9 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. Approvals for proprotein convertase subtilisin/kexin type 9 inhibitors will be granted for a period of six months.

Treatment Approval Criteria for Praluent (Alirocumab)

1. Patient is 18 years of age or older.
2. Diagnosis of primary hyperlipidemia OR clinical atherosclerotic cardiovascular disease (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 or rosuvastatin* for 90 days AND ezetimibe for 90 days. Take ezetimibe in combination with one of the above statins in attempt to achieve the lowest possible.

    a. Treatment failure is defined as inability to obtain LDL-C less than or equal to 70 mg/dl after receiving each of these medications for at least 90 days.
    b. Give consideration for alternative adjunctive therapies for patients with documented evidence of a contraindication to atorvastatin and rosuvastatin.

Treatment Approval Criteria for Repatha (Evolocumab)

1. Patient is 13 years and older with diagnosis of homozygous familial hypercholesterolemia (HoFH). **OR**
2. Patient is 18 years of age and older with diagnosisof primary hyperlipidemia **OR** clinical atherosclerotic cardiovascular disease (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. Take ezetimibe 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 70 mg/dl after receiving each of these medications for at least 90 days.
    b. Give consideration for alternative adjunctive therapies for patients with documented evidence of a contraindication to atorvastatin and rosuvastatin.

**__Rosuvastatin authorization__: 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 people with a documented diagnosis from above and a statement indicating the pursuance of PCSK9 inhibitor approval to obtain rosuvastatin authorization. Atorvastatin must be used for at least 90 days, prior to receiving a rosuvastatin override.*

Maintenance Therapy Approval Criteria for Praluent (Alirocumab) or Repatha (Evolocumab)

1. Patient must maintain concurrent use with maximally tolerated atorvastatin or rosuvastatin therapy.
    - Consideration for alternative adjunctive therapies may be given for patients 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 primary hyperlipidemia and 30% for HoFH) of LDL-C since initiation of PCSK9 inhibitor therapy. Current LDL-C level will be required for renewal approval at six months.

Medicaid Population

- Fee-for-service (traditional): Only use this form for people enrolled in Medicaid fee-for-service. Using this form for other populations may lead to unnecessary delays in access to treatment.
- Medicaid managed care: Contact the appropriate managed care organization (MCO) for people enrolled in managed care. Refer to the Prescriber MCO Assistance Chart at txvendordrug.com/resources/managed-care to obtain the specific prior authorization instructions and contact information for each MCO.

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 greater than 70mg/dl despite treatment with 90 days of atorvastatin treatment, 90 days of rosuvastatin, and most recently, 90 days of ezetimibe treatment.

☐ Patient 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 patients with primary hyperlipidemia and 30% LDL-C reduction for patients with a diagnosis of HoFH).

Prescribing providers with questions may call the Texas Prior Authorization Call Center at 877-728-3927.

Section 1 – Patient Information

Patient Name (First, Last, MI)	Date of Birth	Medicaid ID

Applicable Drug Allergies

Section 2 – Patient History

Required Diagnosis (Check one of the following):

	Diagnosis of Primary Hyperlipidemia	Date of Diagnosis:
	Clinical Atherosclerotic Cardiovascular Disease	Date of Diagnosis:
	Diagnosis of Homozygous Familial Hypercholesterolemia	Date of

Drug Treatment History (Complete as applicable):

	Drug	**Last Prescriber Dose**	**Start Date**	**End Date** (if applicable)
	Atorvastatin			
	Ezetimibe			
	Rosuvastatin			
Other (List drug name(s) below):				

AddLine RemoveLine**Section3–PCSK9InhibitorPrescr**

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*Requiredforrenewal requestsonly.Musthaveatleast

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rst)PrescriberNPIAddress(Street,City,StateandZIPCode)	

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ax No.with AreaCode Bysigningbelow,I,theprescriber,certifytheinformationprovided aboveisverifiableand accuratetotheb

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