Fee-For-Service Medicaid PCSK9 Inhibitors Prior Authorization Request Form

HHSC VENDOR DRUG PROGRAM

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.

Fee-For-Service Medicaid: this form should only be used for individuals enrolled in fee-for-service Medicaid. Using this form for other individuals may lead to unnecessary delays in access to treatment.
Medicaid managed care: Please contact the appropriate managed care organization (MCO) for individuals enrolled in managed care. Prior authorization information differs by MCO. Please refer to the Prescriber Assistance Chart at TxVendorDrug.com/managed-care/ to obtain the specific prior authorization instructions and contact information.

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**

LDL-C level not at goal → LDL-C >130mg/dL → Request PA for PCSK9 inhibitor → Follow up LDL-C level due with PA renewal at 6 months

90 days rosuvastatin or atorvastatin → 90 days rosuvastatin or atorvastin PLUS 90 days ezetimibe → Continue taking atorvastatin or rosuvastatin PLUS ezetimibe → Begin PCSK9 inhibitor therapy and continue atorvastatin or rosuvastatin

PA approval
PCSK9 INHIBITORS
PREAUTHORIZATION REQUEST
PRESCRIBER FAX FORM

ONLY the prescriber may complete and fax this form. This form is for prospective, concurrent, and retrospective reviews.

Incomplete forms will be returned for additional information. The following documentation is required for preauthorization consideration. For formulary information and to download additional forms, please visit www.bcbs tx.com/starkids

<table>
<thead>
<tr>
<th>PATIENT INFORMATION</th>
<th>Today’s Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name (First):</td>
<td>Last:</td>
</tr>
<tr>
<td>Patient Address:</td>
<td>City, State, Zip:</td>
</tr>
<tr>
<td>M: DOB (mm/dd/yy):</td>
<td>Patient Telephone:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INSURANCE INFORMATION</th>
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<tbody>
<tr>
<td>BCBS ID Number:</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>PRESCRIBER/CLINIC INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescriber Name:</td>
</tr>
<tr>
<td>Specialty:</td>
</tr>
<tr>
<td>Clinic Name:</td>
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<tr>
<td>City, State, Zip:</td>
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PLEASE ATTACH ANY ADDITIONAL INFORMATION THAT SHOULD BE CONSIDERED WITH THIS REQUEST

Patient’s Diagnosis (please check one of the following):

- [ ] Diagnosis of Heterozygous Familial Hypercholesteremia
- [ ] Clinical Atherosclerotic Cardiovascular Disease
- [ ] Diagnosis of Homozygous Familial Hypercholesteremia
- [ ] Other, please specify ICD code plus description

Date of diagnosis:

Medication Requested: Strength:

Dosing Schedule: Quantity per Month:

Please indicate PSCK9 Treatment Status: [ ] Initial [ ] Continuation; Date of treatment initiation:

☐ Expedited/Urgent Review Requested: By checking this box and signing below, I certify that applying the standard review time frame may seriously jeopardize the life or health of the patient or the patient’s ability to regain maximum function.

Signature of prescriber or prescriber’s designee: Date:

Section 1. Drug Treatment History (complete as applicable):

<table>
<thead>
<tr>
<th>Drug</th>
<th>Last prescribed dose</th>
<th>Start date (mm/dd/ccyy)</th>
<th>End date* (if applicable) (mm/dd/ccyy or N/A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>atorvastatin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ezetimibe</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>rosvastatin</td>
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<td></td>
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<tr>
<td>other (please specify):</td>
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<td></td>
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<tr>
<td>other (please specify):</td>
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<tr>
<td>other (please specify):</td>
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</tbody>
</table>

*For current therapy, indicate “N/A” for “End date”.
Section 2. Laboratory Information:

<table>
<thead>
<tr>
<th>LDL-C prior to initiation of PCSK9 treatment:</th>
<th>Date level obtained: ________________________ (for first time requests, level must be from previous 60 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>______________ mg/dL</td>
<td></td>
</tr>
<tr>
<td>Current LDL-C: ____________________________ mg/dL*</td>
<td>Date level obtained: ____________________________ (level must be from previous 60 days)</td>
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</table>

*Required for renewal requests only. Must have at least a 50% reduction in LDL-C compared to LDL-C level prior to PCSK9 treatment initiation for patients with HeFH and at least a 30% reduction in LDL-C for patients with HoFH for renewal approval.

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 or mail this form to:
Texas Medicaid
c/o Prime Therapeutics LLC, Clinical Review Department
1305 Corporate Center Drive
Eagan, Minnesota 55121

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TOLL FREE
Fax: 877.243.6930   Phone: 855.457.1200

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