

**NC Medicaid  
Outpatient Pharmacy  
Prior Approval Criteria  
PCSK9 Inhibitors**

**Effective Date: January 1, 2016  
Revised Date: February 6, 2023**

**DRAFT**

**Therapeutic Class Code: M4T**

**Therapeutic Class Description: Antihyperlipidemic - PCSK9 Inhibitors**

**Medications**

**Leqvio® (inclisiran)**

**Praluent® (alirocumab)**

**Repatha™ (evolocumab)**

**Eligible Beneficiaries**

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

**EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age**

**42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

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**EPSDT and Prior Approval Requirements**

- a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

*NCTracks Provider Claims and Billing Assistance Guide:*

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

*EPSDT provider page:*

<https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents>

**Criteria for all PCSK9 Inhibitors**

- Beneficiary must be 18 years of age or older  
**AND**
- Beneficiary is currently taking maximum dose atorvastatin (generic for Lipitor®) or rosuvastatin (generic for Crestor®) for their age and has completed 90 days of treatment. **Provider must verify adherence through consultation with the beneficiary's pharmacy.**
  - Failure to reach target LDL-C (at least 50% reduction from baseline OR if no baseline is available: 70 mg/dL for beneficiaries with clinical ASCVD and <100 mg /dL for beneficiaries with primary hyperlipidemia, including HeFH, and no history of clinical ASCVD) after taking atorvastatin (generic for Lipitor®) or rosuvastatin (generic for Crestor®) for 90 days.
  - For intolerance to atorvastatin (generic for Lipitor®) or rosuvastatin (generic for Crestor®), trial and failure of both of these statins at lower dose must be utilized and documented.
    - Clinically significant intolerance or allergic reaction to statin treatment must be documented and attached to the prior authorization. Examples of significant intolerance includes severe muscle pain, significant liver abnormalities, and rhabdomyolysis. Intolerance does not include fatigue, cognitive impairment, or mild aches.
- AND**
- Baseline LDL labs prior to any treatment and labs after previous treatments showing inadequate control on statins **AND ezetimibe** must be attached to the initial prior authorization request.
- AND**
- Beneficiary must continue both PCSK9 Inhibitor and high dose atorvastatin (generic for Lipitor®) or rosuvastatin (generic for Crestor®) to continue therapy unless otherwise approved due to intolerance.

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**Criteria for alirocumab (Praluent®)**

- Beneficiary must have a diagnosis Heterozygous Familial Hypercholesterolemia (HeFH) or Homozygous Familial Hypercholesterolemia (HoFH)
  - For beneficiaries with a diagnosis of HeFH, the age limit is 8 years and older.
- OR
- Beneficiary must have clinical atherosclerotic cardiovascular disease, defined as acute coronary syndromes, or a history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease of atherosclerotic origin.
- OR
- Beneficiary must have a diagnosis of Severe Primary Hyperlipidemia (defined as LDL-C  $\geq$  190 mg/dL)

**Criteria for evolocumab (Repatha®)**

- Beneficiary must have a diagnosis Heterozygous (HeFH) or Homozygous Familial Hypercholesterolemia (HoFH)
  - For beneficiaries with a diagnosis of HoFH or HeFH, the age limit is 10 years and older.
- OR
- Beneficiary must have clinical atherosclerotic cardiovascular disease defined as acute coronary syndromes, or a history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease of atherosclerotic origin, or is being treated for reduction of Major Adverse Cardiac Events (MACE).
- OR
- Beneficiary must have a diagnosis of Severe Primary Hyperlipidemia (defined as LDL-C  $\geq$  190 mg/dL)

**Criteria for inclisiran (Leqvio®)**

- Beneficiary must have a diagnosis Heterozygous Familial Hypercholesterolemia (HeFH)

OR

- Beneficiary must have clinical atherosclerotic cardiovascular disease defined as acute coronary syndromes, or a history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease of atherosclerotic origin.

OR

- Beneficiary must have a diagnosis of Hypercholesterolemia (LDL-C  $\geq$  190 mg/dL)

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**Continuation Criteria for evolocumab (Repatha®), alirocumab (Praluent®) and inclisiran (Leqvio®)**

- Provider has submitted documentation that indicates a positive clinical response to therapy  
**AND**
- Beneficiary continues to receive other lipid-lowering adjunctive therapy  
**AND**
- Beneficiary is not receiving more than one PSCK9 inhibitor at a time

**References**

1. Drug Effectiveness Review Project: Propoprotein Convertase Subtilisin Kexin type 9 (PCSK9) Inhibitors Draft Original Report, May 2015, Kim Peterson, MS, Brittany Holzhammer, MPH, Marian McDonagh, PharmD
2. Drug Effectiveness Review Project: Propoprotein Convertase Subtilisin Kexin type 9 (PCSK9) Inhibitors Draft Original Report-Appendixes and Evidence Tables, May 2015, Kim Peterson, MS, Brittany Holzhammer, MPH, Marian McDonagh, PharmD
3. Praluent® (alirocumab) package insert. ©2015 Regeneron Pharmaceuticals, Inc./ sanofi-aventis U.S. LLC. Updated April 2019. Updated April 2021
4. Blom DJ, Hala T, Bolognese M, et al. A 52-week Placebo-Controlled Trial of Evolocumab in Hyperlipidemia. N Engl J Med 2014; 370:1809-19.
5. Repatha™ (evolocumab) package insert v2. ©2015 Amgen, Inc. updated 12/2017. Updated September 2021
6. Leqvio (inclisiran) package insert. Novartis Pharmaceuticals. East Hanover, NJ. June 2024.

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**Criteria Change Log**

|            |   |
|------------|---|
| 01/01/2016 | Criteria effective date   |
| 06/12/2018 | Added new GCN 41834   |
| 05/21/2020 | <p>Removed GCN's</p> <p>Updated links to EPSDT and Billing Guide</p> <p>Removed under 75 years of age</p> <p>Added: AND ezetimibe</p> <p>Removed: Beneficiary's LDL level is greater or equal to 130 mg/dl</p> <p>Added: Failure to reach target LDL-C (at least 50% reduction from baseline OR if no baseline is available: 70 mg/dL for beneficiaries with clinical ASCVD and &lt;100 mg /dL for beneficiaries with primary hyperlipidemia, including HeFH, and no history of clinical ASCVD)</p> <p>For Praluent:</p> <p>Removed: such as heart attack or stroke</p> <p>Added: defined as acute coronary syndromes, or a history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease of atherosclerotic origin.</p> <p>OR</p> <p>Beneficiary must have a diagnosis of Severe Primary Hyperlipidemia (defined as LDL-C <math>\geq</math> 190 mg/dL)</p> <p>For Repatha:</p> <p>Removed: such as heart attack or stroke</p> <p>Added: defined as acute coronary syndromes, or a history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease of atherosclerotic origin.</p> <p>OR</p> <p>Beneficiary must have a diagnosis of Severe Primary Hyperlipidemia (defined as LDL-C <math>\geq</math> 190mg/dL)</p> |
| 10/01/2021 | Added continuation criteria   |
| 02/06/2023 | Added Homozygous Familial Hypercholesterolemia (HoFH) for Praluent  |
| 02/06/2023 | Updated ages for HeFH and HoFH for Repatha  |
| xx/xx/xxxx | <p>Added criteria for inclisiran (Leqvio®)</p> <p>Updated age for HeFH for Praluent</p> <p>Added MACE Indication for Repatha</p> <p>Removed requirement for ezetimibe treatment</p>   |