NC Medicaid
Outpatient Pharmacy **Effective Date: June 23, 2023**
Prior Approval Criteria

Therapeutic Class Code: M4V, M4W
Therapeutic Class Description: Antihyperlipidemic – ATP Citrate Lyase, Antihyperlipidemic- ACLY and Choles Absorp Inhib

Medication
Nexletol
Nexlizet

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 beneficiary'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 beneficiary'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.

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.
***Basic Medicaid Billing 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 Initial Coverage of Nexletol:

- Beneficiary is ≥ 18 years of age;

AND

- Beneficiary has diagnosis of heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD) 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.

AND

- Beneficiary has failed to achieve a target LDL-C (at least 50% reduction from baseline OR if no baseline is available: <70 mg/dL for beneficiaries with ASCVD and <100 mg /dL for beneficiaries with HeFH, and no history of ASCVD) despite physician attestation that the beneficiary is adherent to maximally-tolerated doses of statins for at least 90 days duration prior to the lipid panel demonstrating suboptimal reduction;

AND

- Therapy will be used in conjunction with maximally-tolerated doses of a statin;

AND

- Therapy will not be used with concurrent doses of simvastatin > 20 mg or pravastatin > 40 mg;

- Initial approval shall be for up to 6 months.

Criteria for Initial Coverage of Nexlizet:

- Beneficiary is ≥ 18 years of age;

AND

- Beneficiary has diagnosis of heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD) 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;

AND

- Beneficiary has failed to achieve a target LDL-C (at least 50% reduction from baseline OR if no baseline is available: <70 mg/dL for beneficiaries with ASCVD and <100 mg /dL for beneficiaries with HeFH, and no history of ASCVD) despite physician attestation that the beneficiary is adherent to maximally-tolerated doses of statins for at least 90 days duration prior to the lipid panel demonstrating suboptimal reduction;

  AND

- Therapy will be used in conjunction with maximally-tolerated doses of a statin;

  AND

- Therapy will not be used with concurrent doses of simvastatin > 20 mg or pravastatin > 40 mg;

  AND

- Beneficiary does not have a hypersensitivity to ezetimibe (Zetia®);

  AND

- Therapy will also not be used with concurrent fibrate therapy (excluding fenofibrate)

- Initial approval shall be for up to 6 months.

Criteria for Continuation of Coverage of Nexletol & Nexlizet:

- Beneficiary continues to meet the initial approval criteria listed above;

  AND

- Beneficiary is absent of unacceptable toxicity from therapy. (Examples of unacceptable toxicity include the following: hyperuricemia, tendon rupture);

  AND

- Laboratory analysis demonstrate a reduction in LDL-C when compared to the baseline values (prior to initiating bempedoic acid or bempedoic acid/ezetimibe);

  AND

- Beneficiary has shown continued adherence to maximally-tolerated statin dosage

References

1. Nexletol [package insert]. Ann Arbor, MI; Esperion; February 2020.
2. Nexlizet [package insert]. Ann Arbor, MI; Esperion; February 2020.
3. Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013. DOI: 10.1016/j.jacc.2013.11.002. Available at: http://www.acc.org/guidelines#doctype=Guidelines.
4. Grundy S, Stone NJ, Baily A, et al. 2018

AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol. J Am Coll Cardiol. 2018. DOI: 10.1016/j.jacc.2018.11.003. Available at http://www.acc.org/guidelines#doctype=Guidelines.

Criteria Change Log

06/23/2023	Criteria effective date