NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Ctexli

Effective Date: November 5, 2026

Therapeutic Class Code: D7A
Therapeutic Class Description: CHOLELITHOLYTIC AGENTS - BILE THERAPY

Medication
Ctexli

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
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.

IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, 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 initial approval

- Beneficiary is 18 years of age or older; **AND**
- Beneficiary has a confirmed diagnosis of Cerebrotendinous Xanthomatosis (CTX). This diagnosis needs to be established by one of the following:
    - **Genetic Testing:** A molecular genetic test showing a pathogenic variant in the CYP27A1 gene. **OR**
    - **Laboratory Tests:** Elevated serum cholestanol levels. **AND**
- Ctexli must be prescribed by or in consultation with a specialist who treats patients with Cerebrotendinous Xanthomatosis, such as a geneticist, neurologist, ophthalmologist, or metabolic specialist. **AND**
- Ctexli is not being prescribed concurrently with Chenodal. **AND**
- Ctexli is not being prescribed concurrently with bile acid salts unless clinically appropriate **AND**
- The prescriber agrees to monitor the patient's ALT, AST, and bilirubin levels annually or as clinically indicated **AND**
- Baseline liver transaminase (ALT and AST) and total bilirubin levels must be obtained before initiating Ctexli treatment.

Procedures

- Approve for up to 6 months.

Criteria for continuation:

- Documentation of a positive response to therapy, such as decreased or stabilized bile alcohol levels, reduced signs and symptoms of CTX, or a reduction in plasma cholestanol levels. **AND**
- The beneficiary should not have experienced unacceptable toxicity or treatment-restricting adverse effects from the medication

Procedures

- Approve for up to 6 months.
- Preferred Drug List (PDL) criteria also apply if requested medication is on the PDL. (ex. try and fail preferred(s)first or a clinical reason the preferred(s) cannot be tried or other criteria as noted on the PDL).

References

1. Ctexli [package insert].Foster City, CA; Mirum Pharmaceuticals, Inc.; February 2025

Criteria Change Log

11/05/2026	Criteria effective date