

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2025 P 2373-1
Program	Prior Authorization/Medical Necessity
Medication	Ctexli™ (chenodiol)
P&T Approval Date	6/2025
Effective Date	9/1/2025

**1. Background:**

Ctexli (chenodiol) is a bile acid indicated for treatment of cerebrotendinous xanthomatosis (CTX) in adults.

**2. Coverage Criteria<sup>a</sup>:****A. Initial Authorization**

1. **Ctexli** will be approved based on **all** of the following criteria:

a. Diagnosis of cerebrotendinous xanthomatosis (cholestanol storage disease)

**-AND-**

b. Disease is confirmed by the presence of pathogenic variant(s) in the CYP27A1 gene

**-AND-**

c. Prescribed by or in consultation with **one** of the following:

- (1) Endocrinologist
- (2) Geneticist
- (3) Neurologist

**Authorization will be issued for 12 months.**

**B. Reauthorization**

1. **Ctexli** will be approved based on **both** of the following criteria:

a. Documentation of positive clinical response to **Ctexli** therapy

**-AND-**

b. Prescribed by or in consultation with **one** of the following:

- (1) Endocrinologist
- (2) Geneticist
- (3) Neurologist

**Authorization will be issued for 12 months.**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

### 3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

### 4. Reference:

1. Ctexli [package insert]. Foster City, CA: Mirum Pharmaceuticals, Inc.; July 2024.
2. Stelten BML, Dotti MT, Verrips A, Elibol B, Falik-Zaccai TC, Hanman K, Mignarri A, Sithole B, Steiner RD, Verma S, Yahalom G, Zubarioglu T, Mochel F, Federico A. Expert opinion on diagnosing, treating and managing patients with cerebrotendinous xanthomatosis (CTX): a modified Delphi study. Orphanet J Rare Dis. 2021;16(1):353. doi:10.1186/s13023-021-01980-5.
3. DeBarber A, Kisanuki Y, Nobrega P, Himes R, Jayadev S, Bernat J, Prakash V, Gibson J, Larson A, Sgobbi P, Murphy E, Fedor B, Wong Po Foo C, Dutta R, Imperiale M, Garner W, Vig P, Perez S, Ramdhani R, Saute J, Duell PB. Evaluation of Chenodeoxycholic Acid Treatment in Adult Patients with Cerebrotendinous Xanthomatosis: A Randomized, Placebo-Controlled Phase 3 Study [abstract].

Program	Prior Authorization/Medical Necessity - Ctexli (chenodiol)
<b>Change Control</b>	
6/2025	New program.