UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3162-3
Program	Step Therapy
Medication	Chenodal™ (chenodiol)
P&T Approval Date	1/2022, 1/2023, 1/2024
Effective Date	4/1/2024

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try ursodiol before providing coverage for Chenodal for radiolucent gallstones.

Chenodal (chenodiol) is indicated for patients with radiolucent stones in well-opacifying gallbladders, in whom selective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age. Ursodiol is used for treatment of cholelithiasis via the dissolution of radiolucent cholesterol gallstones.

Members currently on Chenodal therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. <u>Radiolucent Gallstones</u>

1. **Chenodal** will be approved based on **one** of the following criteria:

   a. History of failure, contraindication, or intolerance to ursodiol (document date of trial and list reason for therapeutic failure, contraindication, or intolerance)

   -OR-

   b. **<u>Both</u>** of the following:

      (1) Patient is currently on Chenodal therapy

      -AND-

      (2) Patient has **<u>not</u>** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a Retrophin, Inc. sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Chenodal*

   * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a Retrophin, Inc. sponsored program **<u>shall</u>**

be required to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

B. Other Diagnoses

1. **Chenodal** will be approved

Authorization will be issued for 12 months.

[a] 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.

4. References:

1. Chenodal [package Insert].San Diego, CA: Retrophin, Inc.; June 2015.

Program	Step Therapy – Chenodal (chenodiol)
Change Control	
1/2022	New program.
1/2023	Annual review with no change to coverage criteria.
1/2024	Annual review with no change to coverage criteria.