AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Chenodal® (chenodiol)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

NOTE: *Total approval duration should not exceed 24 months (2 years). The safety and efficacy of chenodiol has not been evaluated beyond 2 years of treatment.

Recommended Dosage: Oral: Initial: 250 mg twice daily for 2 weeks, then increase dose by 250 mg/day each week until the recommended maintenance dose or maximum tolerated dose is achieved; maintenance: 13 to 16 mg/kg/day in 2 divided doses. Note: Dosages <10 mg/kg are usually ineffective and may increase the risk of cholecystectomy. If diarrhea occurs, temporarily decrease dose; once symptoms resolve, attempt to reinstate the previous dose. Discontinue treatment if there is no response by 18 months; safe use beyond 24 months has not been established

Body Weight		Recommended tablets/day	Dose range mg/kg
Pounds (lb)	Kilograms (kg)		
100-130	45-58	3	13-17
131-185	59-75	4	13-17
186-200	76-90	5	14-18
201-235	91-107	6	14-18
236-275	108-125	7	14-18

Quantity Limits: 7 tablets per day

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

- ❑ Member is 18 years of age or older
- ❑ Prescribed by or in consultation with a gastroenterologist
- ❑ Member is using for gallstone dissolution
- ❑ Provider must submit documentation to confirm member has a well-opacifying gallbladder with radiolucent stones
- ❑ Provider attests member has an increased surgical risk due to systemic disease or age
- ❑ Member has had at least a 6-month trial with or is currently taking an ursodiol product at up to maximally indicated doses (8-10 mg/kg/day PO in 2-3 divided doses) unless contraindicated or clinically significant adverse effects are experienced **(verified by chart notes and/or pharmacy paid claims)**
- ❑ Provider attests member will receive periodic liver function monitoring due to the potential for hepatotoxicity during treatment with Chenodal®
- ❑ Females of reproductive potential must have a negative pregnancy test prior to start of Chenodal®
- ❑ Provider attests females of childbearing potential and males capable of fathering a child will use effective method of contraception while using Chenodal®
- ❑ Provider attests member does **NOT** have any of the following:
  - Large or nonfloatable stones
  - Calcified (radiopaque) or radiolucent bile pigment stones
  - Preexisting hepatic impairment
  - Known hepatocyte dysfunction or bile ductal abnormalities (such as but not limited to intrahepatic cholestasis, primary biliary cirrhosis, or sclerosing cholangitis)
  - Gallbladder confirmed as nonvisualizing after two consecutive single doses of dye
  - Gallstone complications or compelling reasons for gallbladder surgery (such as but not limited to unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary gastrointestinal fistula)

Reauthorization: 12 months (up to 24 months total treatment).

Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet **ALL** initial authorization criteria

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- ❑ Member must meet **ONE** of the following:
  - ❑ Member has experienced partial (or complete) dissolution of stones **(submit documentation that repeat imaging studies confirm member has partial dissolution of gallstones)**
  - ❑ Member has **NOT** experienced a partial dissolution, and provider will discontinue therapy with the requested drug if response is not seen by 18 months of treatment
- ❑ Member has experienced an absence of unacceptable toxicity from requested medication (e.g., hepatotoxicity)

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.***