Clinical Policy Title:	chenodiol
Policy Number:	RxA.065
Drug(s) Applied:	Chenodal®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Radiolucent Gallstones (must meet all):

1. Presence of radiolucent stones in well-opacifying gallbladders;
2. Age ≥ 18 years;
3. Trail and failure of at least 6-month trial of ursodiol, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Member is not a candidate for surgery (e.g., due to systemic disease or age);
5. Dose does not exceed 18 mg per kg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Radiolucent Gallstones (must meet all**):**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Total treatment duration does not exceed 24 months;
4. If request is for a dose increase, new dose does not exceed 18 mg per kg per day.

Approval Duration
Commercial: 12 months (up to 24 months total treatment)
Medicaid: 12 months (up to 24 months total treatment)

References
Not Applicable

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1) Clinical policy title was updated as "chenodiol". 2) Line of business policies applies to All	02/03/2021	03/09/2021

lines of business. 3) Continuation therapy criteria II.A.1. rephrased to “Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy”.		
Policy was reviewed: 1) Initial Approval Criteria, I.A.3: Updated trial and failure criteria from Failure of a 6-month trial of ursodiol, unless contraindicated or clinically significant adverse effects are experienced to Failure of at least 6-month trial of ursodiol, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced. 2) Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".	12/06/2021	01/17/2022
Policy was reviewed.	09/30/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023