

Clinical Policy Title:	chenodiol
Policy Number:	RxA.065
Drug(s) Applied:	Chenodal®
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
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. Trial and failure of at least 6 months of ursodiol, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
3. Member is not a candidate for surgery (e.g., due to systemic disease or age).

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Radiolucent Gallstones (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 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: <ol style="list-style-type: none"> 1) Clinical policy title was updated as "chenodiol". 2) Line of business policies applies to All 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". 	02/03/2021	03/09/2021

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 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
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed age restrictions. 2. Removed dose restrictions. 3. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 4. Removed other reauthorization requirements including positive response to therapy. 5. Updated approval duration verbiage. 	08/28/2024	09/13/2024