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| 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. Trial 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 |

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.

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| 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 |