Clinical Policy Title:	trientine tetrahydrochloride
Policy Number:	RxA.501
Drug(s) Applied:	Cuvrior™, trientine
Original Policy Date:	03/06/2020
Last Review Date:	12/05/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Wilson's Disease (must meet all)**:**

1. Diagnosis of Wilson's disease;
2. Member is de-coppered and tolerant to penicillamine.
3. Member had been receiving penicillamine for at least one (1) year prior to Cuvrior™.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Wilson's Disease (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

References

1. Palumbo CS, Schilsky ML. Clinical practice guidelines in Wilson disease. Ann Transl Med. Apr 2019; 7(Suppl 2): S65. doi: 10.21037/atm.2018.12.53. Available at: https://pubmed.ncbi.nlm.nih.gov/31179302/. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to all lines of business. 2. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 3. References were updated.	09/13/2020	12/7/2020

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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Policy was reviewed: 1. Initial and Continued Therapy Approval Criteria was updated to remove HIM approval duration. 2. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. References were reviewed and updated.	09/18/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of Wilson's disease to Diagnosis of Wilson's disease with one of the following (a or b): a. For Syprine®: Member is intolerant of penicillamine; b. For Cuvrior™: Member is de-coppered and tolerant to penicillamine. 2. Initial Approval Criteria, I.A.2.b: Updated to include new age criteria For Cuvrior™: Age ≥ 18 years. 3. Initial Approval Criteria, I.A.4: Updated to include new criteria pertaining to indication Wilson's disease, For Cuvrior™: Member had been receiving penicillamine for at least one (1) year prior to Cuvrior™; 4. Initial Approval Criteria, I.A.5.b: Updated to include new dosing criteria For Cuvrior™: 3,000 mg per day. 5. Continued Therapy Approval, II.A.3.b: Updated to include new dosing criteria For Cuvrior™: 3,000 mg per day. 6. References were reviewed and updated.	06/16/2022	07/18/2022
Policy was reviewed: 1. References were reviewed and updated.	08/03/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 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 reauthorization requirement for positive response to therapy. 5. Updated approval duration verbiage.	08/28/2024	09/13/2024

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6. References were reviewed and updated.		
Policy was reviewed: 1. Removed Syprine® from the PA policy and its related trial and failure criteria.	12/05/2024	N/A

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