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| **Clinical Policy Title:** | trientine hydrochloride, trientine tetrahydrochloride |
| **Policy Number:** | RxA.501 |
| **Drug(s) Applied:** | Syprine®, Cuvrior™ |
| **Original Policy Date:** | 03/06/2020 |
| **Last Review Date:** | 08/28/2024 |
| **Line of Business Policy Applies to:** | All lines of business (except Medicare) |

## Criteria

**I. Initial Approval Criteria**

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

1. 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. For Syprine®: Trial and failure of penicillamine (Depen® is preferred) unless contraindicated or clinically significant adverse effects are experienced;
3. For Cuvrior™: 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 |
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| Policy established. | 01/2020 | 03/06/2020 |
| Policy was reviewed:<br>1. Policy title table was updated: Line of business policy applies was updated to all lines of business.<br>2. Continued therapy criteria II.A.1 was rephrased to "Currently receiving | 09/13/2020 | 12/7/2020 |

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| medication that has been authorized by RxAdvance…".<br>3. References were updated. | | |
| Policy was reviewed:<br>1. Initial and Continued Therapy Approval Criteria was updated to remove HIM approval duration.<br>2. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".<br>3. References were reviewed and updated. | 09/18/2021 | 12/07/2021 |
| Policy was reviewed:<br>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):<br>a. For Syprine®: Member is intolerant of penicillamine;<br>b. For Cuvrior™: Member is de-coppered and tolerant to penicillamine.<br>2. Initial Approval Criteria, I.A.2.b: Updated to include new age criteria For Cuvrior™: Age ≥ 18 years.<br>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™;<br>4. Initial Approval Criteria, I.A.5.b: Updated to include new dosing criteria For Cuvrior™: 3,000 mg per day.<br>5. Continued Therapy Approval, II.A.3.b: Updated to include new dosing criteria For Cuvrior™: 3,000 mg per day.<br>6. References were reviewed and updated. | 06/16/2022 | 07/18/2022 |
| Policy was reviewed:<br>1. References were reviewed and updated. | 08/03/2022 | 10/19/2022 |
| Policy was reviewed. | 10/19/2023 | 10/19/2023 |
| Policy was reviewed:<br>1. Removed age restrictions.<br>2. Removed dose restrictions.<br>3. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. | 08/28/2024 | 09/13/2024 |

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| 4. Removed reauthorization requirement for positive response to therapy.<br>5. Updated approval duration verbiage.<br>6. References were reviewed and updated. | | |