UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2325-2
Program	Prior Authorization/Medical Necessity
Medication	Cuvrior™ (trientine tetrahydrochloride)*
P&T Approval Date	2/2024, 2/2025
Effective Date	5/1/2025

1. Background:

Cuvrior (trientine tetrahydrochloride) is a copper chelator indicated for the treatment of adult patients with Wilson's disease who are de-coppered and tolerant to penicillamine. Chelating agents (e.g., pencillamine, trientine hydrochloride) are well-established as the standard treatment of Wilson's disease. Cuvrior (trientine tetrahydrochloride) has only been studied for maintenance treatment in patients with Wilson's disease who are pencillamine tolerant.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Cuvrior*** will be approved based upon **all** of the following criteria:

   a. Diagnosis of Wilson's disease

   -AND-

   b. Patient is de-coppered [i.e., serum non-ceruloplasmin copper (NCC) level ≥ 25 and ≤ 150 mcg/L]

   -AND-

   c. Patient is tolerant to penicillamine

   -AND-

   d. Patient will discontinue penicillamine before starting therapy with Cuvrior

   -AND-

   e. History of intolerance, failure or contraindication to trientine hydrochloride

   -AND-

   f. Prescribed by a hepatologist.

Authorization will be issued for 12 months.

B. Reauthorization

1. **Cuvrior** will be approved based on **both** the following criteria:

   a. Documentation of positive clinical response to Cuvrior therapy (e.g., increased 24-hour urinary copper excretion from baseline, normalization of serum free copper, prevention of or improvement in symptoms)

   -AND-

   b. Prescribed by a hepatologist.

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*Cuvrior is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. Reference:

1. Cuvrior [package insert]. Chicago, IL: Orphalan; April 2022.
2. Trientine hydrochloride [package insert]. Parsippany, NJ: Teva Pharmaceuticals; January 2022.
3. Schilsky ML, Roberts EA, Bronstein JM, et al. A multidisciplinary approach to the diagnosis and management of Wilson disease: 2022 Practice Guidance on Wilson disease from the American Association for the Study of Liver Diseases. *Hepatology*. Published online December 7, 2022.
4. Saroli Palumbo C, Schilsky ML. Clinical practice guidelines in Wilson disease. *Ann Transl Med*. 2019;7(Suppl 2):S65.

Program	Prior Authorization/Medical Necessity - Cuvrior (trientine tetrahydrochloride)
Change Control	
2/2024	New program.
2/2025	Annual review with no changes to coverage criteria. Updated background and references.