	TTER HEALTH®		<b>*ae</b>	etna <sup>™</sup>		
Coverage Policy/Guideline						
Name: Penicillamine, Tri		, Trientine	Page:	1 of 3		
Effective Date: 10/1/2023			Last Review Date:	8/17/2023		
Applica	□Illinois	□Florida	□New Jersey			
Applies to:	⊠Maryland	⊠Florida Kids	⊠Pennsylvania Kids			
	□Michigan		□Kentucky PRMD			

## Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Penicillamine and Trientine under the patient's prescription drug benefit.

## **Description:**

# FDA-APPROVED INDICATIONS

# **Cuvrior (trientine tetrahydrochloride)**

Cuvrior is indicated for the treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine.

## **Penicillamine**

Penicillamine is indicated in the treatment of Wilson's disease, cystinuria, and in patients with severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy. Available evidence suggests that Penicillamine is not of value in ankylosing spondylitis.

## **Trientine hydrochloride**

Trientine hydrochloride is indicated in the treatment of patients with Wilson's disease who are intolerant of penicillamine. Clinical experience with Trientine hydrochloride is limited and alternate dosing regimens have not been well-characterized; all endpoints in determining an individual patient's dose have not been well defined. Trientine hydrochloride and penicillamine cannot be considered interchangeable. Trientine hydrochloride should be used when continued treatment with penicillamine is no longer possible because of intolerable or life endangering side effects.

Unlike penicillamine, Trientine hydrochloride is not recommended in cystinuria or rheumatoid arthritis. The absence of a sulfhydryl moiety renders it incapable of binding cystine and, therefore, it is of no use in cystinuria. In 15 patients with rheumatoid arthritis, Trientine hydrochloride was reported not to be effective in improving any clinical or biochemical parameter after 12 weeks of treatment.

Trientine hydrochloride is not indicated for treatment of biliary cirrhosis.

# **Applicable Drug List:**

Preferred: Penicillamine tablet

Non-Preferred: Penicillamine Capsule, Trientine, Cuvrior

## Policy/Guideline:

# **Criteria for Initial Approval:**

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The requested drug will be covered with prior authorization when the following criteria are met:

 The request is for Cuprimine (penicillamine capsules) or Depen (penicillamine tablets)

## **AND**

- The requested drug is being prescribed for the treatment of Wilson's disease
  OR
- o The requested drug is being prescribed for the treatment of cystinuria

## OR

 The requested drug is being prescribed for the treatment of severe, active rheumatoid arthritis in a patient who has failed to respond to an adequate trial of conventional therapy

[Note: Conventional therapy for rheumatoid arthritis may include disease-modifying antirheumatic drugs

(DMARDs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine.]

## OR

The request is for trientine hydrochloride (e.g., Syprine)

## AND

The requested drug is being prescribed for the treatment of Wilson's disease
 AND

o The patient has experienced an intolerance to penicillamine

#### ΛP

The request is for Cuvrior (trientine tetrahydrochloride) for the treatment of stable
 Wilson's disease

## AND

o The patient is de-coppered

## AND

o The patient is tolerant to penicillamine

# **Approval Duration and Quantity Restrictions:**

**Initial and Renewal Approval:** 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

## **References:**

- 1. Cuprimine [package insert]. Bridgewater, New Jersey: Bausch Health US, LLC; October 2020.
- 2. Cuvrior [package insert]. Chicago, Illinois: Orphalan SA; April 2022.
- 3. Depen [package insert]. Somerset, New Jersey: Meda Pharmaceuticals Inc; January 2019.
- 4. Syprine [package insert]. Bridgewater, New Jersey: Bausch Health US, LLC; September 2020.

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- 5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed March 3, 2023.
- 6. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/\_(cited:\_03-03-2023).
- 7. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res.* 2021;73(7):924-939.