MEDICAL MUTUAL®

# Drug Policy

| Policy: | Cuprimine ® (penicillamine capsules) Prior Approval | Annual Review Date: 02/17/2022<br><br>Last Revised Date: 02/17/2022 |
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## OVERVIEW

Cuprimine (penicillamine) is a chelating agent indicated for 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. Penicillamine removes excess copper in patients with Wilson's disease. Penicillamine also reduces excess cystine excretion in cystinuria. Penicillamine is a disease-modifying antirheumatic drug (DMARD) indicated in severe, active RA that has not responded to other conventional agents. The mechanism of action of penicillamine in rheumatoid arthritis is unknown although it appears to suppress disease activity.

## POLICY STATEMENT

This policy involves the use of Cuprimine. Prior authorization is recommended for pharmacy benefit coverage of Cuprimine. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Cuprimine as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Cuprimine be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cuprimine is recommended in those who meet the following criteria:

### Food and Drug Administration (FDA)-Approved Indications

1. **Wilson's Disease.** Approve for 1 year if the patient meets the following criteria (A and B):
   - **A)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician; AND
   - **B)** The patient meets ONE of the following criteria (I or ii):

**i.** The patient has tried Depen [penicillamine tablets]) and per the prescribing physician, Depen therapy was ineffective or not tolerated; OR
**ii.** Per the prescribing physician, Depen tablets are contraindicated.

**2. Cystinuria.** Approve for 1 year if the patient meets the following criteria (A and B):
**A)** Treatment with conservative measures (e.g. high fluid intake, sodium and protein restriction, urinary alkalinization) was ineffective, not tolerated, or is contraindicated; AND
**B)** Treatment with Depen tablets was ineffective, not tolerated, or is contraindicated.

**3. Rheumatoid Arthritis.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
**A)** Patient has failed at least two conventional medications (methotrexate, sulfasalazine, leflunomide, hydroxychloroquine, etc); AND
**B)** Treatment with Depen tablets was ineffective, not tolerated, or is contraindicated; AND
**C)** The medication is prescribed by or in consultation with a rheumatologist.

**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 1 year (365 days)
**B)** *Extended Approval:* 1 year (365 days) if patient meets criteria and has had a beneficial response to therapy according to the prescriber such as: (1) improved neurologic condition or improved/stable liver findings for Wilson's Disease, (2) decreased concentration of urinary cysteine or decreased kidney stone frequency or severity per the prescriber for Cystinuria, (3) less joint pain, morning stiffness, or fatigue, improved function or activities of daily living, decreased soft tissue swelling in joints or tendon sheaths, improved laboratory values, or reduced dosage of corticosteroids for Rheumatoid Arthritis).

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Cuprimine has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

**1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES

1. Cuprimine® capsules [prescribing information]. Bridgewater, NJ: Acton Pharma, a division of Valeant Pharmaceuticals North America LLC; March 2018.
2. Saag KG, Saag, KG, Bridges, L, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Rheum. 2016;68(1):1-26.
3. Roberts EA, Schilsky ML. AASLD practice guidelines diagnosis and treatment of Wilson Disease: An Update. J Hepatol. 2008;47(6):2089-111.
4. Fernci P, Czlonkowska A, Stremmel W, et al. EASL clinical practice guidelines: Wilson's disease. J Hepatol. 2012;56(3):671-85.
5. Biyani CS, Cartledge JJ. Cystinuria—diagnosis and management. European Urology. 2006;4:175-183.
6. Depen [prescribing information]. Somerset, NJ: Meda Pharmaceuticals Inc.; April 2009.