

Clinical Pharmacy Program Guidelines for Copper Chelating Agents

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| Program | Prior Authorization- Copper chelating Agents |
| Medication | Copper Chelating Agents [Syprine (trientine), Cuprimine (penicillamine), Depen Titratable (penicillamine)] |
| Issue Date | 9/2014 |
| Pharmacy and Therapeutics Approval Date | 10/2017 |
| Effective Date | 11/2017 |

1. Background:

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| Cuprimine (penicillamine) | Wilson's Disease – Indicated in the treatment of Wilson's disease |
| | Cystinuria – Indicated in the treatment of cystinuria |
| | Rheumatoid Arthritis – Indicated in the treatment of severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy |
| Depen Titratable (penicillamine) | Wilson's Disease – Indicated in the treatment of Wilson's disease |
| | Cystinuria – Indicated in the treatment of cystinuria |
| | Rheumatoid Arthritis – Indicated in the treatment of severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy |
| Syprine (trientine) | Wilson's Disease – Indicated in the treatment of Wilson's disease who are intolerant of penicillamine |

2. Coverage Criteria:

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| <p>A. <u>Depen Titratable</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. <u>One</u> of the following diagnoses:</p> <ul style="list-style-type: none"> (1) Wilson's disease (i.e., hepatolenticular degeneration) (2) Cystinuria (3) Severe active rheumatoid arthritis <p>Authorization will be issued for 12 months.</p> |
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2. Reauthorization

***Note this section only applies for diagnosis of severe active rheumatoid arthritis only. For Wilson's disease and cystinuria, patient would continue to go through initial authorization for a diagnosis check only**

a. **Depen Titratable** will be approved based upon the following criterion:

- (1) Documentation of positive clinical response to Depen Titratable therapy

Authorization will be issued for 12 months.

B. Cuprimine

1. Initial Authorization

a. **One** of the following diagnoses:

- (1) Wilson's disease (i.e., hepatolenticular degeneration)
- (2) Cystinuria
- (3) Severe active rheumatoid arthritis

-AND-

b. History of failure or intolerance to Depen (penicillamine)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Cuprimine** will be approved based upon the following criterion:

- (1) Documentation of positive clinical response to Cuprimine therapy

Authorization will be issued for 12 months.

C. Syprine

1. Initial Authorization

a. Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

-AND-

b. History of failure, contraindication, or intolerance to Depen (penicillamine) or Cuprimine (penicillamine)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Syprine** will be approved based upon the following criterion:

- (1) Documentation of positive clinical response to Syprine therapy

Authorization will be issued for 12 months.

3. References:

1. Cuprimine Prescribing Information. Aton Pharma, Inc., November 2015.
2. Syprine Prescribing Information. Aton Pharma, Inc., December 2016.
3. Depen Titratable Prescribing Information. Meda Pharmaceuticals. April 2009.

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| Program | Prior Authorization- Copper Chelating Agents |
| Change Control | |
| Date | Change |
| 9/2014 | New guideline. |
| 12/2015 | <ul style="list-style-type: none"> • Added Depen Titratable formulation to the policy due to addition to the Preferred Drug List. Prior authorization required. • Changed approval length to 1 year • Added Depen Titratable to list of references |
| 6/2016 | Updated policy template. Added reauthorization criteria. |
| 6/2017 | Annual review. Updated references. |
| 9/2017 | Added note under reauthorization criteria for Depen Titratable that criteria will only apply to diagnosis of severe active rheumatoid arthritis to allow for Dx to Rx implementation |