Clinical Pharmacy Program Guidelines for Copper Chelating Agents

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization- Copper chelating Agents</th>
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<tbody>
<tr>
<td>Medication</td>
<td>Copper Chelating Agents [Syprine (trientine), Cuprimine (penicillamine), Depen Titratable (penicillamine)]</td>
</tr>
<tr>
<td>Markets in Scope</td>
<td>Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina</td>
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<tr>
<td>Issue Date</td>
<td>9/2014</td>
</tr>
<tr>
<td>Pharmacy and Therapeutics Approval Date</td>
<td>6/2020</td>
</tr>
<tr>
<td>Effective Date</td>
<td>8/2020</td>
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1. **Background:**

Depen and Cuprimine are 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.

Syprine is indicated in the treatment of patients with Wilson’s disease who are intolerant of penicillamine.

2. **Coverage Criteria:**

   A. **Depen Titratable**

      1. **Initial Authorization**

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

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

         **Authorization will be issued for 12 months.**

      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. **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. **References:**


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<tr>
<td><strong>Change Control</strong></td>
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<tr>
<td>Date</td>
<td>Change</td>
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<tr>
<td>9/2014</td>
<td>New guideline.</td>
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</table>
| 12/2015               | • 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. |
| 6/2018                | Annual review. No changes to criteria.      |
| 6/2019                | Annual review. Formatted background to align with other programs. |
| 6/2020                | Annual review. Updated references.          |

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