Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2020**
Policy Number: PA.CP.PHAR.438	**Effective Date: 01/15//2020** **Revision Date: 01/15/2020**
Policy Name: Trientine (Syprine)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

New Policy Created

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Trientine (Syprine)

Reference Number: PA.CP.PHAR.438
Effective Date: 01/2020
Last Review Date: 01/2020

Revision Log

Description
Trientine (Syprine®) is a chelating agent.

FDA Approved Indication(s)
Syprine is indicated for the treatment of patients with Wilson's disease who are intolerant of penicillamine.

Limitation(s) of use: Unlike penicillamine, Syprine is not recommended in cystinuria or rheumatoid arthritis. Syprine is not indicated for treatment of biliary cirrhosis.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Syprine is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Wilson's Disease (must meet all)**:**

1. Diagnosis of Wilson's disease;
2. Failure of penicillamine at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed one of the following (a or b):
   a. Age > 12 years: 2,000 mg per day;
   b. Age ≤ 12 years: 1,500 mg per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Wilson's Disease (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. Age > 12 years: 2,000 mg per day;
   b. Age ≤ 12 years: 1,500 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53;
B. Biliary cirrhosis;
C. Cystinuria;
D. Rheumatoid arthritis.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Depen, Cuprimine® (penicillamine)	Wilson's disease 250 mg PO QID; adjust to achieve urinary copper excretion 0.5-1 mg/day	Wilson's disease: 2 g/day (750 mg/day if pregnant)

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity

- Boxed warning(s): none reported

Appendix D: General Information

- Clinical experience with Syprine 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.
- Syprine and penicillamine cannot be considered interchangeable.
- The absence of a sulfhydryl moiety renders Syprine incapable of binding cystine and, therefore, it is of no use in cystinuria. In 15 patients with rheumatoid arthritis, Syprine was reported not to be effective in improving any clinical or biochemical parameter after 12 weeks of treatment.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Wilson's disease	Age ≤ 12 years: 500-750 mg/day PO in divided doses two, three, or four times daily Age > 12 years: 750-1,250 mg/day PO in divided doses two, three, or four times daily	Age ≤ 12 years: 1,500 mg/day Age > 12 years: 2,000 mg/day

VI. Product Availability

Capsule: 250 mg

VII. References

1. Syprine Prescribing Information. Bridewater, NJ: Valeant Pharmaceuticals: December 2016. Available at: www.syprine.com. Accessed August 26, 2019.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: http://www.clinicalpharmacology-ip.com/. Accessed August 26, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New Policy Created	01/2020	