BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Trientine (Syprine)

Policy Number: 9.310
Version Number: 1
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth- MCO ☒ MassHealth-ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **trientine (Syprine)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications unless otherwise excluded
Exclusion Criteria	None
Required Medical Information	1. A diagnosis of Wilson's disease confirmed through genetic testing or presence of three of the following diagnostic features: a. Presence of Kayser-Fleisher rings b. Serum ceruloplasmin (CPN) <20mg/dL

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	c. 24-hour urine Cooper >40mcg d. Liver biopsy with copper dry weight >250mcg/g; AND 2. An intolerance to a trial of penicillamine (Depen) tablets
Age Restrictions	None
Prescriber Restriction	Medication is prescribed by or in collaboration with a rheumatologist or a provider specializing in the treatment of Wilson's disease
Coverage Duration	Initial: 6 months Reauthorization: 1 year
Other criteria	Reauthorization: 1. Member is responding to treatment; AND 2. Member is not experiencing intolerable adverse effects; AND 3. A failed trial of zinc salts; AND 4. Member is following a strict low copper diet

Clinical Background Information and References

1. Cuprimine [Package Insert]. Whitehouse Station, NJ: Merck & Co., Inc.; 2004.
2. Depen [Package Insert]. Somerset, NJ: Meda Pharmaceuticals Inc.; 1988.
3. Penicillamine. In DRUGDEX®. Micromedex Solutions Website. http://www.micromedexsolutions.com. Accessed March 10, 2014.
4. Penicillamine: Pediatric drug information. UptoDate Website. http://www.uptodate.com. Accessed June 13, 2016.
5. Cystine Stones. UptoDate Website. http://www.uptodate.com. Accessed June 13, 2016.
6. Wilson disease. UptoDate Website. http://www.uptodate.com. Accessed June 13, 2016.
7. Singh JA, Furst DE, Bharat A, et al. 2012 Update of the 2008 American College of Rheumatology recommendation for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care & Research. 2012; 64(5):625-39.
8. DeBerardinis RJ, Coughlin CR, and Kaplan P. Penicillamine therapy in pediatric cystinuria: experience from a cohort of American children. J Urol. 2008; 180(6):2620-3.
9. Roberts EA, Schilsky ML, and the American Association for the Study of Liver Diseases (AASLD). Diagnosis and treatment of Wilson disease: An update. Hepatology. 2008; 47(6):2089-2111.
10. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis & Rheumatism. 2008; 59(6):762-84.
11. Syprine [package insert]. Bridgewater, NJ:Valeant; 2016.

12. Schilsky, M et al. Wilson Disease: Treatment and prognosis. UpToDate. Last update: November 29,2016. Accessed June 18, 2018.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2020	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.065 Trientine (Syprine) Policy retired, new policy created	1/1/2021	P&T Committee

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as

the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.