

Syprine (trientine)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Syprine (trientine)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Syprine (trientine) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Wilson's Disease as confirmed by **two** of the following (AASLD 2022):
 - A. Serum ceruloplasmin less than 20 mg/dL;
 - B. Presence of Kayser-Fleischer rings;
 - C. 24-hour urinary copper is greater than 40 µg/day;
 - D. Liver biopsy findings consistent with Wilson's Disease;
 - E. Genetic testing findings consistent with Wilson's Disease.

Key References:

- Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
- Committee on Drugs, American Academy of Pediatrics. Treatment guidelines for lead exposure in children. *Pediatrics*. 1995; 96:155-60.
- DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 13, 2022.
- DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- Fraenkel L, Bathon J, England B, et al. 2021 American College of Rheumatology (ACR) Guideline for the treatment of rheumatoid arthritis. *Arthritis Care & Research*. Vol. 73, No. 7, July 2021, pp 924-939. Available at <https://www.rheumatology.org/Portals/0/Files/2021-ACR-Guideline-for-Treatment-Rheumatoid-Arthritis-Early-View.pdf>. Accessed October 13, 2022.
- Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
- NCT03539952. ClinicalTrials.gov. National Institute of Health. U.S. National Library of Medicine. Available at <https://clinicaltrials.gov/ct2/show/NCT03539952?term=nct03539952&draw=2&rank=1>. Accessed on October 13, 2022.
- Pearle MS, Goldfarb DS, Assimos DG, et. al. American Urological Association. Medical management of kidney stones: AUA guideline. *J Urol*. 2014;192(2):316-24. Reaffirmed 2019. Available from: <https://www.auanet.org/education/guidelines/management-kidney-stones.cfm>. Accessed on: October 13, 2022.
- Qaseem A, Dallas P, Forciea MA, et al. Dietary and Pharmacologic Management to Prevent Recurrent Nephrolithiasis in Adults: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med*. 2014; 161:659-667. Available from: <https://www.acponline.org/clinical-information/guidelines>. Accessed on: October 13, 2022.
- Roberts EA, Schilsky ML. AASLD Practice Guidelines: Diagnosis and treatment of Wilson disease: an update. *Hepatology*. 2008;47(6):2089-111. Available from: http://www.aasld.org/sites/default/files/guideline_documents/Wilson%20Disease2009.pdf. Accessed on: October 13, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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