Penicillamine

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Depen Titratabs (penicillamine) 250mg tablets	8 tablets per day*

*In the treatment of cystinuria may approve up to 16 capsules/tablets per day.

APPROVAL CRITERIA

Requests for penicillamine agents (Depen Titratabs) 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 2008):
   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;

OR

II. Individual has a diagnosis of cystinuria; **AND**
III. Individual is using to prevent the formation of cystine kidney stones; **AND**
IV. Individual has had a trial and inadequate response or inability to adhere to a conservative treatment program including increased fluid intake (Pearle et al., 2014; Qaseem et al., 2014), restriction of sodium and protein intake (AUA 2014; Qaseem et al., 2014), and urinary alkalinization (Pearle et al., 2014);

OR

V. Individual has a diagnosis of severe, active rheumatoid arthritis; **AND**
VI. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to three nonbiologic disease modifying anti-rheumatic drugs (DMARDs), such as methotrexate, leflunomide, sulfasalazine, or hydroxychloroquine (ACR, 2015); **AND**
VII. Individual does not have a history of renal insufficiency;

OR

X. Individual has a diagnosis of lead poisoning (AHFS); **AND**

XI. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to Chemet (succimer) **AND** Calcium disodium versenate (edetate calcium disodium) (AAP, 1995).

Requests for penicillamine agents (Depen Titratabs) may **not** be approved for any of the following:

I. Individual has a prior history of aplastic anemia or agranulocytosis while on penicillamine.

Note: Penicillamine agents have a black box warning for the need of an experienced physician to manage therapy. Physicians using penicillamine should be thoroughly educated on its therapeutic benefits and toxicity. Individuals being treated with penicillamine should be under the close supervision of the physician and instructed to report symptoms of toxicity promptly.

Key References:

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4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. Committee on Drugs, American Academy of Pediatrics. Treatment guidelines for lead exposure in children. *Pediatrics*. 1995; 96:155-60.
6. 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 12, 2020.
7. 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 12, 2020.
8. 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 12, 2020.
9. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2016; 68(1):1-25. Available from: http://onlinelibrary.wiley.com/doi/10.1002/acr.22783/full. Accessed on: October 12, 2020.
10. U.S. Food & Drug Adminstration. FDA Drug Shortages. Available from: https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Penicillamine (Depen) Titratable Tablets&st=c&tab=tabs-1. Accessed on: October 12, 2020.

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

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