

Penicillamine tablets (generic Depen)

POLICY

I. CRITERIA FOR APPROVAL

Wilson's Disease

An authorization of 6 months for the treatment of Wilson's disease may be granted when all the following criteria are met:

- A. Patient has documented diagnosis of Wilson's disease, which is confirmed by genetic testing results confirming biallelic pathogenic *ATP7B* mutations OR confirmation of at least two of the following clinical features associated with Wilson's disease:
 - i. Presence of Kayser-Fleischer rings
 - ii. Serum ceruloplasmin level < 20 mg/dL
 - iii. Liver biopsy findings consistent with Wilson's disease (e.g., copper dry weight greater than 250 mcg/g)
 - iv. 24-hour urinary copper > 40 mcg/24 hours
- B. Medication is prescribed by, or in consultation with a gastroenterologist, hepatologist, or liver transplant physician
- C. Patient has experienced an inadequate response, intolerance or contraindication to zinc therapy, or zinc would not be an appropriate therapy.

II. CONTINUATION OF THERAPY

An authorization of 6 months for the treatment of Wilson's disease may be granted when all the following criteria are met:

- A. Patient continues to meet initial approval criteria
- B. Documentation of a positive response to treatment as indicated by an improvement in neurologic condition or improved liver findings

III. QUANTITY LIMIT

Penicillamine 250mg tablets has a quantity limit of 8 tablets per day.

IV. REFERENCES

1. Depen [package insert]. Somerset, New Jersey: Meda Pharmaceuticals Inc; July 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed March 21, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 03-21-2024).