

Market Applicability					
Market	GA	KY	MD	NJ	NY
Applicable	NA	NA	NA	X	NA

Penicillamine (Cuprimine, Depen, D-Penamine)

NJ Medicaid

Override(s)	Approval Duration
Prior Authorization	1 year

New Jersey Medicaid

Medications	Quantity Limit
Cuprimine (penicillamine) 250mg capsules Depen Titratabs (penicillamine) 250mg tablets D-Penamine (penicillamine) 125mg tablets	May be subject to quantity limit

Background:

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Wilson disease is a rare autosomal recessive inherited disorder of copper metabolism that is characterized by excessive deposition of copper in the liver, brain, and other tissues. The mainstay of therapy for Wilson disease is pharmacologic treatment with chelating agents such as D-penicillamine and trientine.

Cystinuria is an inherited autosomal recessive disease that is characterized by high concentrations of the amino acid cysteine in the urine, leading to the formation of cystine stones in the kidneys, ureter, and bladder. The foundation of cystine stone prevention is adequate hydration and urinary alkalinization. When this conservative therapy fails, thiol drugs, such as D-penicillamine are added to the regimen.

Rheumatoid arthritis (RA) is the most common type of autoimmune arthritis. D-penicillamine appears to have a clinical and statistical benefit on the disease activity of patients with rheumatoid arthritis.

APPROVAL CRITERIA

Patient has a documented diagnosis of one of the following:

A. Wilson's disease **AND** treatment with Depen® (penicillamine titratable) was ineffective, not tolerated, or is contraindicated **OR**

B. Cystinuria **AND**

- 1) Treatment with conservative measures (e.g. high fluid intake, sodium and protein restriction, urinary alkalinization) was ineffective, not tolerated, or is contraindicated **AND**

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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2) Treatment with Depen® was ineffective, not tolerated, or is contraindicated **OR**

C. Severe, active Rheumatoid arthritis meeting **ALL** the following:

- 1) Treatment with one month trial of each of the following was ineffective, not tolerated, or is contraindicated: methotrexate, hydroxychloroquine, leflunomide, and sulfasalazine; **AND**
- 2) The patient is not pregnant; **AND**
- 3) The patient does not have a history or other evidence of renal insufficiency

Black Box Warning: Physicians planning to use penicillamine should thoroughly familiarize themselves with its toxicity, special dosage considerations, and therapeutic benefits. Penicillamine should never be used casually. Each patient should remain constantly under the close supervision of the physician. Patients should be warned to report promptly any symptoms suggesting toxicity

Key References:

1. Cuprimine [prescribing information]. Bridgewater, NJ: Aton Pharma. Inc. November 2015
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2018. Updated periodically
3. Suarez-Almazor ME, Spooner C, Belseck E. Penicillamine for treating rheumatoid arthritis. Cochrane Database Syst. Rev. 2000;(4):CD001460. Accessed online 5.18.19
4. Singh JA, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016 Jan;68(1):1-26.

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