Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Penicillamine
(Cuprimine, Depen, D-Penamine)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Cuprimine (penicillamine) 250mg capsules Depen Titratabs (penicillamine) 250mg tablets D-Penamine (penicillamine) 125mg tablets

APPROVAL CRITERIA

Requests for penicillamine agents (Cuprimine, Depen, D-Penamine) 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 (Label; Roberts, 2008):
   A. Serum ceruloplasmin less than 20 mg/dL;
   B. Presence of Kayser-Fleischer rings;
   C. 24-hour urinary copper is great than 40 µg/day;
   D. Liver biopsy findings consistent with Wilson's Disease;
   E. Genetic testing findings consistent with Wilson's Disease;

AND

II. Individual has had a trial and inadequate response or intolerance to Syprine (trientine) (Roberts, 2008);

OR

III. Individual has a diagnosis of cystinuria; **AND**

IV. Individual is using to prevent the formation of cystine kidney stones; AND

V. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as 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 (Pearle et al., 2014; Qaseem et al., 2014), and urinary alkalinization (Pearle et al., 2014); **AND**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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VI. Individual has had a trial and inadequate response or intolerance to Thiola (tiopronin) (Pearle et al., 2014);

OR

VII. Individual has a diagnosis of severe, active rheumatoid arthritis; **AND**

VIII. 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**

IX. 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).

Penicillamine agents (Cuprimine, Depen, D-Penamine) may not be approved for any of the following:

I. Individual has a prior history of aplastic anemia or agranulocytosis while on penicillamine (Cuprimine, Depen, D-Penamine).

Note: 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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.