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 (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;

AND

II. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to Syprine (trientine) (AASLD 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 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); **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 (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to Thiola (tiopronin) (AUA 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).

Requests for 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: 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.

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

Key References:

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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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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