

Commercial/Healthcare Exchange PA Criteria

Effective: January 1, 2020

Prior Authorization: Penicillamine

Products Affected: Cuprimine capsule, Depen tablet, D-penaminate tablet, penicillamine tablet

Medication Description: Penicillamine is a chelating agent indicated for the treatment of Wilson's disease, cystinuria, and in patients with severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy. Penicillamine removes excess copper in patients with Wilson's disease. Penicillamine also reduces excess cystine excretion in cystinuria. Penicillamine is a disease-modifying antirheumatic drug (DMARD) indicated in severe, active RA that has not responded to other conventional agents. The mechanism of action of penicillamine in rheumatoid arthritis is unknown although it appears to suppress disease activity.

Covered Uses:

1. Wilson's Disease
2. Cystinuria
3. Rheumatoid Arthritis (severe), active disease that has failed to respond to conventional therapy.

Exclusion Criteria:

1. Breastfeeding
2. During pregnancy, except for treatment of Wilson's disease and certain cases of cystinuria
3. Patients with history of penicillamine-related aplastic anemia/agranulocytosis
4. Rheumatoid arthritis patients with history or other evidence of renal insufficiency
5. Juvenile rheumatoid arthritis

Required Medical Information:

1. Diagnosis
2. Previous therapies tried/failed

Age Restrictions: N/A

Prescriber Restrictions:

1. Wilson's Disease: Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.
2. Cystinuria: Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders
3. Rheumatoid Arthritis: Prescribed by or in consultation with a rheumatologist.

Coverage Duration: 12 months

Other Criteria:

Wilson's Disease

1. Patient has a diagnosis of Wilson's disease (i.e., hepatolenticular degeneration).

Cystinuria

1. Patient has a diagnosis of cystinuria; **AND**
2. Patient has had previous treatment with conservative measures (e.g. high fluid intake, sodium and protein restriction, urinary alkalinization).

Last Rev. October 21, 2019

Rheumatoid Arthritis

1. Patient has a diagnosis of active rheumatoid arthritis; AND
2. Patient has had a trial and failure with at least two conventional therapies (methotrexate, sulfasalazine, leflunomide, hydroxychloroquine, etc.).

References:

1. Product Information: CUPRIMINE(R) oral capsules, penicillamine oral capsules. Merck & Co, Inc, Whitehouse Station, NJ, 2004.
2. Product Information: DEPEN(R) titratable oral tablets, penicillamine titratable oral tablets. Meda Pharmaceuticals Inc, Somerset, NJ, 2009.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/21/2019