Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Penicillamine (Cuprimine, Depen)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***July 2013 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process Penicillamine (Cuprimine, Depen).

Penicillamine (Cuprimine, Depen) is indicated for the treatment of:

- Wilson's Disease
- Cystinuria
- Patients with severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy

DEFINITIONS

***ATP7B* Gene –** encodes a metal-transporting P-type ATPase, which is mainly expressed in hepatocyte and functions in the transmembrane transport of copper. Absent or reduced function of *ATP7B* protein leads to decreased hepatocellular excretion of copper into bile.

Ceruloplasmin – protein synthesized in the liver which is responsible for copper transport and storage

Cystinuria – rare autosomal recessive defect of the transepithelial transport of cysteine and dibasic amino acids in the kidney and intestine causing profoundly decreased cysteine resorption in the proximal renal tubule. The increased urinary excretion of cysteine results in cysteine crystallization and stone formation.

Kayser-Fleischer Ring – deposition of copper in the periphery of the cornea

Wilson's Disease (or hepatolenticular degeneration) – a rare autosomal recessive genetic disorder of copper metabolism, which is characterized by hepatic and neurological disease.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Penicillamine (Cuprimine, Depen), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. **Wilson's Disease:**
   - Must be prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders or by a hepatologist
   - Must have a diagnosis of Wilson's Disease. Chart documentation describing how diagnosis was confirmed is required. Diagnosis must be confirmed by having documentation of at least one of the following:
     - Hepatic parenchymal copper content of ≥250µg/g dry weight
     - Presence of Kayser-Fleischer Ring in cornea
     - Serum ceruloplasmin level <50mg/L
     - Basal 24-hour urinary excretion of copper >100µg (1.6µmoles)

    - Genetic testing results indicating mutation in ATP7B gene
- Must have baseline (within 6 months) urinalysis, complete blood count (CBC), platelet count, and hemoglobin

2. Cystinuria:

- Must be prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders
- Must have a diagnosis of cystinuria. Chart documentation describing how diagnosis was confirmed (e.g. progress notes, urinary cysteine excretion analysis) is required.
- Must have baseline (within 6 months) urinalysis, complete blood count (CBC), platelet count, and hemoglobin

3. Rheumatoid Arthritis:

- Must be prescribed by a rheumatologist
- Must have a diagnosis of severely active rheumatoid arthritis
- Must have an adequate trial (at least 3 months) of methotrexate with an inadequate response or significant side effect/toxicity or have a contraindication to this therapy
- Must have an adequate trial (at least 3 months) of leflunomide, hydroxychloroquine, minocycline, OR sulfasalazine with an inadequate response or significant side effect/toxicity or have a contraindication to these therapies
- Must have baseline (within 6 months) urinalysis, complete blood count (CBC), platelet count, hemoglobin

Requests for penicillamine (Cuprimine) must be accompanied by the following:

- Chart documentation of an adequate trial of at least 3 months of penicillamine (Depen) with an inadequate response or significant side effects/toxicity
- Chart documentation of the clinical rationale to explain why Depen has not produced the same clinical results as would be expected with Cuprimine (as they are the same chemical entity)

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Depen [prescribing information]. Somerset, NJ: Meda Pharmaceuticals Inc.; April 2009
2. Cuprimine [prescribing information]. Lawrenceville, NJ: Aton Pharma; October 2008
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6. Claes DJ, Jackson E. Cystinuria: mechanisms and management. *Pediatric Nephrology* 012;27(11):2031-2038
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10. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum* 2008;59(6):762-784

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*