

POLICY AND PROCEDURE

POLICY NUMBER: *RX.PA.214.E*

REVISION DATE: *06/14*

PAGE NUMBER: 1 of 3

POLICY TITLE: *Syprine (trientine hcl) and Galzin (zinc acetate)*
DEPARTMENT: *Clinical Pharmacy Services- Utilization Management*
ORIGINAL DATE: *September 2013 (as adopted from UPMC Health Plan)*

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

Product Applicability: *mark all applicable products below:*

COMMERCIAL	<input type="checkbox"/> HMO	<input type="checkbox"/> PPO	Products: <input type="checkbox"/> Small	Exchange: <input type="checkbox"/> Shop	<input checked="" type="checkbox"/> All
			<input type="checkbox"/> Indiv.	<input type="checkbox"/> Indiv.	
			<input type="checkbox"/> Large		
OTHER	<input checked="" type="checkbox"/> Self-funded/ASO				

PURPOSE

The purpose of this policy is to define the prior authorization process for Syprine (trientine hcl) and Galzin (zinc acetate).

Syprine (Trientine hydrochloride) is indicated in the treatment of patients with Wilson’s Disease who are intolerant of penicillamine.

Galzin (Zinc acetate) is indicated for maintenance treatment of patients with Wilson’s disease who have been initially treated with a chelating agent.

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

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 drugs, Syprine (trientine hcl) and Galzin (zinc acetate), are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- 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 $\geq 250\mu\text{g/g}$ dry weight
 - Presence of Kayser-Fleischer Ring in cornea
 - Serum ceruloplasmin level $< 50\text{mg/L}$
 - Basal 24-hour urinary excretion of copper $> 100\mu\text{g}$ (1.6 μmoles)
 - Genetic testing results indicating mutation in ATP7B gene
- Must have an adequate trial of at least 3 months of penicillamine (Depen®), Cuprimine®) with an inadequate response or significant side effects/toxicity or must have a contraindication to this therapy.

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. Syprine [prescribing information]. Lawrenceville, NJ: Aton Pharma; June 2008
2. Galzin [prescribing information]. Sellersville, PA: Teva Pharmaceuticals; November 2005
3. Depen [prescribing information]. Somerset, NJ: Meda Pharmaceuticals Inc.; April 2009
4. Cuprimine [prescribing information]. Lawrenceville, NJ: Aton Pharma; October 2008
5. Roberts EA, Schilsky MI. A practice guideline on Wilson Disease. Hepatology 2003;37(6):1475- 1492
6. Ala A, Walker AP, Ashkan K, et al. Wilson's disease. Lancet 2007;369:397-408
7. Ferenci P, Caca K, Loudianos G, et al. Diagnosis and phenotypic classification of Wilson disease. Liver International 2003;23:139-142

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
<i>Annual review</i>	<i>02/17, 02/18</i>

