cysteamine (Cystaran™)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO119

Description

Cysteamine (Cystaran) is a cystine depleting ophthalmic solution agent indicated for the treatment of corneal cystine crystal accumulation in patients with cystinosis.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
cysteamine (Cystaran)	0.44% ophthalmic solution	Corneal cystine crystals	4 bottles (60 mL)/28 days

Initial Evaluation

I. Cysteamine (Cystaran) may be considered medically necessary when the following criteria below are met:
   A. Medication is prescribed by, or in consultation with, an ophthalmologist; **AND**
   B. A diagnosis of **cystinosis** when the following are met:
      1. Diagnosis has been confirmed with ONE of the following:
         i. Presence of corneal cysteine accumulation; **OR**
         ii. CTNS gene analysis; **OR**
         iii. Elevated intracellular cystine levels (>1nmol cystine/mg protein)

II. Cysteamine (Cystaran) is considered investigational when used for all other conditions.

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Member has exhibited improvement or stability of disease symptoms

Supporting Evidence

I. Cystinosis is a rare, multisystem genetic disorder characterized by the accumulation of cystine in various bodily organs and tissues leading to the potential for severe organ dysfunction. Cystinosis is further classified into three different forms, known as nephropathic cystinosis, intermediate cystinosis, and non-nephropathic (or ocular) cystinosis. Corneal cystine crystal accumulation may present in all three types.

II. Topical cysteamine is prescribed to prevent corneal deposits, as the oral formulation does not reach the cornea due to a lack of corneal vascularization.

III. The diagnosis of cystinosis is confirmed by elevated intraleukocyte cystine content, (i.e. measuring cystine levels in polymorphonuclear leukocytes), detection of CNTS gene mutation, or demonstration of cystine corneal crystals by the slit lamp examination.

Investigational or Not Medically Necessary Uses

There is no evidence to support the use of cysteamine (Cystaran) in any other condition.

References

1. Cystaran [Prescribing Information]. Gaithersburg, MD: Sigma Tau Pharmaceuticals; October 2012.
2. UpToDate, Inc. Cystinosis. UpToDate [database online]. Waltham, MA. Last updated February 27, 2019 Available at: http://www.uptodate.com/home/index.html.
3. National Organization for Rare Disorders. Cystinosis. Available at: https://rarediseases.org/rare-diseases/cystinosis/

Policy Implementation/Update:

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Date Effective	December 2019
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Action and Summary of Changes	Date