Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Cystaran (cysteamine ophthalmic solution)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***June 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 for Cystaran (cysteamine ophthalmic solution).

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

DEFINITIONS

N/A

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, Cystaran (cysteamine ophthalmic solution), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a physician who specializes in the treatment of inherited metabolic disorders or in consultation with this specialist
- Must have a diagnosis of corneal cystine crystal accumulation due to cystinosis. Chart documentation of a clinical work-up to rule out other diagnoses and clinical rationale for the diagnosis and exclusion of other diagnoses must be provided. The diagnosis must be confirmed by all of the following scenarios (chart documentation is required):
    - Elevated baseline white blood cell (WBC) cystine levels > 2 nmol/1/2cystine/mg protein
    - Laboratory result confirming CTNS gene mutation
    - Clinical symptoms consistent with corneal cystine crystal accumulation including photophobia, corneal erosions, or keratopathies
    - Ophthalmologic exam confirming the diagnosis of corneal cystine crystal accumulation due to cystinosis

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 the following:

- Chart documentation that the member's condition has improved based upon the prescriber's assessment while on therapy
- Chart documentation of evaluation of compliance with therapy as Cystaran (cysteamine ophthalmic solution) is dosed every waking hour

Limitations:

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

Quantity Level Limit	
Cystaran	4 bottles (60 mL) per 30 days

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

REFERENCES

1. Cystaran [package insert]. Gaithersburg, MD: Sigma-Tau Pharmaceuticals, Inc.; October 2012.
2. Gahl WA, Kuehl EM, Iwata F, Lindblad A, Kaiser Kupfer MI. Minireview Corneal crystals in nephropathic cystinosis: natural history and treatment with cysteamine eyedrops. Mol Genet Metab, 2000;71(1 2):100-120.
3. Iwata F, Kuehl EM, Reed GF, McCain LM, Gahl WA. A randomized, clinical trial of topical cysteamine disulfide (cystamine) versus free thiol (cysteamine) in the treatment of corneal cystine crystals in cystinosis. Mol Genet and Metab, 1998;64:237-242.
4. Kaiser Kupfer MI, Fujikawa L, Kuwabara T, Jain S, Gahl WA. Removal of corneal crystals by topical cysteamine in nephropathic cystinosis. N Engl J Med, 1987;316(13):775-779.
5. Kaiser Kupfer MI, Gazzo MA, Datiles MB, Caruso RC, Kuehl EM, et al. A randomized placebo controlled trial of cysteamine eye drops in nephropathic cystinosis. Arch Ophthalmol, 1990;108(5):689-693.
6. Tsilou ET, Thompson D, Lindblad AS, Reed GF, Rubin B, et al. A multicentre, randomized, double masked, clinical trial of a new formulation of topical cysteamine for the treatment of corneal cystine crystals in cystinosis. Br J Ophthalmol, 2003;87(1):28-31.

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*