Clinical Policy: Cysteamine ophthalmic (Cystaran)

Reference Number: PA.CP.PMN.130
Effective Date: 04.17.19
Last Review Date: 04.19

Revision Log

Description
Cysteamine (Cystaran™) ophthalmic solution is a cystine-depleting agent.

FDA Approved Indication(s)
Cystaran is indicated for the treatment of corneal cystine crystal accumulation in patients with cystinosis.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Cystaran is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Corneal Cystine Crystal Accumulation (must meet all)**:**

1. Diagnosis of cystinosis;
2. Prescribed by or in consultation with an ophthalmologist;
3. Presence of corneal cystine accumulation;
4. Dose does not exceed 1 drop in each eye every hour while awake (1 bottle/week).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Corneal Cystine Crystal Accumulation (must meet all)**:**

1. Currently receiving medication via PA Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 drop in each eye every hour while awake (1 bottle/week).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Corneal cystine crystal accumulation	1 drop in each eye every waking hour	1 drop/eye/hour during waking hours

VI. Product Availability

Ophthalmic solution: 6.5 mg/mL of cysteamine hydrochloride equivalent to 4.4 mg/mL of cysteamine (0.44%)

VII. References

1. Cystaran Prescribing Information. Gaithersburg, MD: Leadiant Biosciences, Inc., May 2018. Available at: http://www.cystaran.com/. Accessed February 7, 2019.
2. Cystinosis. National Organization for Rare Disorders website. https://rarediseases.org/rare-diseases/cystinosis/. Published 1986. Updated 2017. Accessed February 7, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.19	