Clinical Policy Title:	cysteamine ophthalmic
Policy Number:	RxA.85
Drug(s) Applied:	Cystaran®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Cystaran® is indicated for the treatment of corneal cystine crystal accumulation in patients with cystinosis.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Cysteamine ophthalmic (Cystaran®)	Corneal cystine crystal accumulation	1 drop in each eye every waking hour	1 drop/eye/hour during waking hours

Dosage Forms

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

Clinical Policy

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

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
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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

APPENDIX B: Therapeutic Alternatives
Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None.

- Boxed Warning(s):
  - None.

APPENDIX D: General Information

- Cystaran® is the only FDA-approved ophthalmic treatment of corneal cystine crystal accumulation in people with cystinosis. Treatment with Cystaran® should be started as soon as cystinosis has been diagnosed by doctor and cystine crystals have been found within the corneas.
- Cystaran® contains benzalkonium chloride, which may be absorbed by soft contact lenses. Contact lenses should be removed prior to application of solution and may be reinserted 15 minutes following its administration.
- The most frequently reported ocular adverse reactions occurring in ≥ 10% of patients were sensitivity to light, redness, and eye pain/irritation, headache and visual field defects.

References

1. Cystaran® Prescribing Information. Amityville, NY: Hi-tech Pharmacal Co., Inc. April 2020. Available at http://www.cystaran.com/for_hcps.php. Accessed February 02, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 02, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Policy was reviewed: 1. Clinical policy title was updated. 2. Commercial and Medicaid approval duration was added for both initial and continued therapy criteria. 3. Continued therapy criteria II.A.1 was rephrased to "Member is currently	02/02/2021	03/09/2021

receiving medication...". 4. Appendix D was updated. 5. References were reviewed and updated.		