

Clinical Policy: Cysteamine Ophthalmic (Cystaran)

Reference Number: ERX.NPA.111

Effective Date: 06.01.19

Last Review Date: 05.20

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 cysteine accumulation;
4. Dose does not exceed 1 drop in each eye every hour while awake (1 bottle per week).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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 per week).

Approval duration: 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---------------------------------------|--------------------------------------|-------------------------------------|
| Corneal cysteine 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

- Cystaran Prescribing Information. Gaithersburg, MD: Leadiant Biosciences, Inc., May 2018. Available at <http://www.cystaran.com/>. Accessed February 7, 2020.
- Cystinosis. National Organization for Rare Disorders website. <https://rarediseases.org/rare-diseases/cystinosis/>. Published 1986. Updated 2017. Accessed February 7, 2020.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|----------|-------------------|
| Policy created | 02.08.19 | 05.19 |
| 2Q 2020 annual review: no significant changes; references reviewed and updated. | 02.07.20 | 05.20 |

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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