

Clinical Policy: Cysteamine (Cystaran)

Reference Number: HIM.PA.107

Effective Date: 08/17

Last Review Date: XX/XX

Line of Business: Health Insurance Marketplace

[Coding Implications](#)
[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

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

Policy/Criteria

Provider must submit documentation (including office chart notes and lab results) 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. Presence of corneal cystine accumulation;
3. Prescribed by or in consultation with an ophthalmologist;
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 HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Cystinosis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response 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 health plan benefit and documentation supports positive response to therapy.

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

2. Refer to HIM.PA.21 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 – HIM.PHAR.21 or evidence of coverage documents;

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

V. References

1. Cystaran Prescribing Information. Amityville, NY: Hi-Tech Pharmacal Co., Inc., October 2012. Available at <http://www.cystaran.com/>. Accessed April 24, 2017.
2. Cystinosis. National Organization for Rare Disorders website. <https://rarediseases.org/rare-diseases/cystinosis/>. Published 1986. Updated 2017. Accessed April 2017.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|-----------------------------------|-------|-------------------|
| Policy created. | 04/17 | 08/17 |

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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