Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 05/01/2022**
Policy Number: PA.CP.PMN.130	**Effective Date: 04/2019** **Revision Date: 04/2022**
Policy Name: Cysteamine ophthalmic (Cystaran, Cystadrops)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

2Q 2022 annual review: references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Cysteamine ophthalmic (Cystaran, Cystadrops)

Reference Number: PA.CP.PMN.130
Effective Date: 04/2019
Last Review Date: 04/2022

Revision Log

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

FDA Approved Indication(s)
Cystaran and Cystadrops are 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 & Wellness® that Cystaran and Cystadrops are **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 one of the following (a or b):
   a. Cystaran: 1 drop in each eye every hour while awake (1 bottle perweek);
   b. Cystadrops: 1 drop in each eye 4 times a day while awake (1 bottle perweek).

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 & 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 one of the following (a or b):
   a. Cystaran: 1 drop in each eye every hour while awake (1 bottle per week);
   b. Cystadrops: 1 drop in each eye 4 times a day while awake (1 bottle per week).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & 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

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Cystaran (cysteamine)	1 drop in each eye every waking hour	1 drop/eye/hour during waking hours
Cystadrops (cysteamine)	1 drop in each eye, 4 times a day during waking hours	See dosing regimen

VI. Product Availability

Drug Name	Availability
Cystaran (cysteamine)	Ophthalmic solution: 6.5 mg/mL of cysteamine hydrochloride equivalent to 4.4 mg/mL of cysteamine (0.44%)
Cystadrops (cysteamine)	Ophthalmic solution containing 3.8 mg/mL of cysteamine (0.37%) in 5 mL bottle

VII. References

1. Cystaran Prescribing Information. Gaithersburg, MD: Leadiant Biosciences, Inc., April 2020. Available at: http://www.cystaran.com/. Accessed January 13, 2022.
2. Cystadrops Prescribing Information. Lebanon, NJ: Recordati Rare Diseases Inc.; August 2020. Available at: https://www.cystadrops.com. Accessed January 13, 2022.
3. Cystinosis. National Organization for Rare Disorders website. https://rarediseases.org/rare-diseases/cystinosis/. Published 1986. Updated 2020. Accessed January 13, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04/2019	
2Q 2020 annual review: added appendix C; references reviewed and updated	04/2020	
2Q 2021 annual review: added Cystadrops to policy; references reviewed and updated.	04/2021	
2Q 2022 annual review: references reviewed and updated.	04/2022	