

Clinical Pharmacy Program Guidelines for Cystaran, Cystadrops

Program	Prior Authorization
Medication	Cystaran™ (cysteamine) ophthalmic solution, Cystadrops® (cysteamine) ophthalmic solution
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	7/2013
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

1. Background:

Cystaran (cysteamine 0.44% ophthalmic solution) and Cystadrops (cysteamine 0.37% ophthalmic solution) are cystine depleting agents indicated for the treatment of corneal cystine crystal accumulation in patients with cystinosis.

2. Coverage Criteria:

<p>A. <u>Authorization</u></p> <p style="margin-left: 40px;">1. Cystaran or Cystadrops will be approved based on the following criterion:</p> <p style="margin-left: 80px;">a. Diagnosis of cystinosis</p> <p style="margin-left: 40px;">Authorization will be issued for 12 months.</p>

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Cystaran [package insert]. Gaithersburg, MD: Leadiant Biosciences, Inc.; April 2020.

2. Cystadrops [package insert]. Lebanon, NJ: Recordati Rare Diseases; August 2020.

Program	Program type – Prior Authorization – Cystaran (cysteamine), Cystadrops (cysteamine)
Change Control	
Date	Change
7/2013	New criteria.
7/2014	Annual review. No changes to the criteria.
10/2014	Modification to implementation date
7/2015	Annual review with no change to criteria.
6/2016	Annual review with no change to criteria. Updated background and references.
6/2017	Annual review with no change to criteria
9/2017	Removed reauthorization criteria and clinical criteria other than diagnosis check to allow for Dx to Rx implementation
6/2018	Annual review. No change to criteria.
6/2019	Annual review. No change to criteria.
5/2020	Annual review. Updated reference.
10/2020	Added Cystadrops to criteria