

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2024 P 1023-14
Program	Prior Authorization/Notification
Medication	Cystaran® (cysteamine) ophthalmic solution, Cystadrops® (cysteamine) ophthalmic solution
P&T Approval Date	7/2013, 7/2014, 7/2015, 6/2016, 6/2017, 6/2018, 6/2019, 6/2020, 10/2020, 11/2021, 11/2022, 11/2023, 11/2024
Effective Date	2/1/2025

**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<sup>a</sup>:**

<p><b>A. <u>Initial Authorization</u></b></p> <p>1. <b>Cystaran or Cystadrops</b> will be approved based on <b>both</b> of the following criteria:</p> <p style="margin-left: 40px;">a. Diagnosis of cystinosis</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="margin-left: 40px;">b. Treatment of corneal cystine crystal accumulation</p> <p><b>Authorization will be issued for 12 months.</b></p> <p><b>B. <u>Reauthorization</u></b></p> <p>1. <b>Cystaran or Cystadrops</b> will be approved based upon the following criterion:</p> <p style="margin-left: 40px;">a. Documentation of positive clinical response to therapy</p> <p><b>Authorization will be issued for 12 months.</b></p> <p><sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</p>
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**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.; February 2022.
2. Cystadrops [package insert]. Lebanon, NJ: Recordati Rare Diseases; September 2020.

Program	Prior Authorization/Notification - Cystaran (cysteamine), Cystadrops (cysteamine)
<b>Change Control</b>	
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.
6/2018	Annual review with no change to criteria.
6/2019	Annual review with no change to criteria.
6/2020	Annual review with no changes to criteria or reference.
10/2020	Added Cystadrops to criteria.
11/2021	Annual review. Updated references.
11/2022	Annual review. Added state mandate language. Updated references.
11/2023	Annual review. No changes.
11/2024	Annual review. No changes.