

[OFFICE LETTERHEAD]

[Date]

[Contact Name]

[Contact Title]

[Name of Insurance Company]

[Insurance Address]

Re: Letter of Medical Necessity for CYSTARAN® (cysteamine ophthalmic solution) 0.44%

Patient Name: **[Patient Name]**

Patient Date of Birth: **[Patient DOB]**

Policy Number: **[Policy Number]**

Group Number: **[Group Number]**

Dear **[Contact Name]**,

I am writing on behalf of my patient **[Patient Name]**, to document the medical necessity of CYSTARAN® (cysteamine ophthalmic solution) 0.44% for **[HIS/HER]** diagnosis of cystinosis and the treatment of corneal cystine crystals associated with the disease. CYSTARAN is an FDA approved cystine-depleting agent specifically indicated for treating corneal cystine crystals in both adults and children with cystinosis. ¹

Summary of Patient's Diagnosis:

- **[Description of genetic test that supports diagnosis of cystinosis]**
- **[Slit lamp exam or ophthalmologic assessment reports that demonstrate corneal cystine crystals]**

Summary of Patient's History:

- **[Description of symptoms related to the cornea]**
- **[Description of other symptoms related to cystinosis that may be relevant for treatment choice]**
- **[If patient has previously received CYSTARAN, treatment initiation date and response]**
- **[List of previous prescription medications related to corneal cystine crystals and response]**
- **[If not previously mentioned, rationale for not using prescription medications that are requested by insurance plan]**

In my medical opinion, **[initiating/continuing]** treatment with CYSTARAN for **[Patient Name]** is both appropriate and medically necessary at this time to treat **[HIS/HER]** corneal crystal accumulation.

Based on the above facts, and my clinical judgment, I am confident that you will agree that CYSTARAN is medically necessary and the appropriate therapeutic choice for **[PATIENT NAME]**.

For any questions or further discussion, please feel free to reach out to me at **[phone number]**.

Sincerely,

[HCP Name and participating provider number]

Enclosures: **[List of documentation described in above letter]**

Resources:

1. CYSTARAN® (cysteamine ophthalmic solution) 0.44% [prescribing information]. Rockville, MD, Leadiant Biosciences, Inc.; Current approved PI
2. Gahl, W et al. Cystinosis. *New England Journal of Medicine*. 2002; 347(2): 111-121.
3. Bäumner S, Weber LT. Nephropathic Cystinosis: Symtopms, Treatment, and Perspectives of a Systemic Disease. *Front Pediatr*. 2018;6:58.