STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYSTEAMINE HYDROCHLORIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYSTEAMINE HCL	CYSTARAN CYSTADROPS		33485 40466	GPI-10 (8680552510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystinosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient require treatment for corneal cystine crystal accumulation or deposits?

   If yes, **approve for 12 months for the requested drug by GPID or GPI-14 with a quantity limit as follows:**
   - **Cystaran: #15mL (4 bottles) per 28 days.**
   - **Cystadrops: #5mL (4 bottles) per 28 days.**

   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **CYSTEAMINE HYDROCHLORIDE (Cystaran/Cystadrops)** requires the following rule(s) be met for approval:
   A. You have cystinosis (a type of genetic disorder where a substance called cysteine builds up in body organs)
   B. You require treatment for corneal cystine crystal accumulation or deposits (build up of cysteine in the eye)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

CYSTEAMINE HYDROCHLORIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cystaran/Cystadrops.

REFERENCES

- Cystaran [Prescribing Information]. Gaithersburg, MD: Leadiant Biosciences, Inc.; May 2018.
- Cystadrops [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases Inc.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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