Reference number
2090-A

SPECIALTY GUIDELINE MANAGEMENT

CYSTARAN (cysteamine ophthalmic solution)
CYSTADROPS (cysteamine ophthalmic solution)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Cystaran
Cystaran is indicated for the treatment of corneal cystine crystal accumulation in patients with cystinosis.

Cystadrops
Cystadrops is indicated for the treatment of corneal cystine crystal deposits in adults and children with cystinosis.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: assay detecting increased cystine concentration in leukocytes or genetic testing results supporting the diagnosis.

III. CRITERIA FOR INITIAL APPROVAL

Cystinosis
Authorization of 12 months may be granted for treatment of corneal cystine crystal accumulation when all of the following criteria are met:
A. Diagnosis of cystinosis was confirmed by the presence of increased cystine concentration in leukocytes or by genetic testing; and
B. Member has corneal cystine crystal accumulation.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who are responding to therapy met by either of the following criteria:
A. Member has experienced a decrease in corneal cystine crystal accumulation; or
B. Member did not experience an increase in corneal cystine crystal accumulation.

V. REFERENCES

1. Cystaran [package insert]. Gaithersburg, MD: Leadiant Biosciences, Inc.; February 2022.

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2. Cystadrops [package insert]. Lebanon, NJ: Recordati Rare Diseases Inc.; August 2020.
3. Ivanova E, De Leo MG, De Matteis MA, Levtchenko E. Cystinosis: clinical presentation, pathogenesis, and treatment. *Pediatr Endocrinol Rev.* 2014;12(1):176-184.

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