

| Reference number |
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| 2090-A           |

## SPECIALTY GUIDELINE MANAGEMENT

### CYSTARAN (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 is indicated for the treatment of corneal cystine crystal accumulation in patients with cystinosis.

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

##### **Cystinosis**

Indefinite authorization may be granted for treatment of corneal cystine crystal accumulation when all of the following criteria are met:

1. Diagnosis of cystinosis was confirmed by the presence of increased cystine concentration in leukocytes or by genetic testing
2. Member has corneal cystine crystal accumulation

##### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

##### IV. REFERENCES

1. Cystaran [package insert]. Gaithersburg, MD: Sigma-Tau Pharmaceuticals, Inc.; October 2012.
2. Ivanova E, De Leo MG, De Matteis MA, Levtchenko E. Cystinosis: clinical presentation, pathogenesis, and treatment. *Pediatr Endocrinol Rev.* 2014;12(1):176-184.