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. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review: leukocyte cystine assay or genetic testing results supporting diagnosis.

III. CRITERIA FOR INITIAL APPROVAL
A. 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

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

V. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

VI. REFERENCES