

SPECIALTY GUIDELINE MANAGEMENT

CYSTAGON (cysteamine bitartrate)

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

Cystagon is indicated for the management of nephropathic cystinosis in children and adults.

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

II. CRITERIA FOR INITIAL APPROVAL

Nephropathic cystinosis

Indefinite authorization may be granted for treatment of nephropathic cystinosis when the diagnosis of cystinosis was confirmed by the presence of increased cystine concentration in leukocytes or by genetic testing.

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Cystagon [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; July 2007.