Reference number
2089-A

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

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

II. REQUIRED DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests: assay detecting increased cystine concentration in leukocytes or genetic testing results supporting diagnosis.
B. Continuation requests: lab results or chart notes documenting a positive response to therapy (e.g., improvement, stabilization, or slowing of disease progression for serum creatinine, calculated creatinine clearance, leukocyte cystine concentration, or maintained growth [height]).

III. CRITERIA FOR INITIAL APPROVAL

Nephropathic cystinosis
Authorization of 12 months may be granted for treatment of nephropathic cystinosis 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 will not use Cystagon in combination with Procysbi.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for neprhopathic cystinosis who are responding to therapy (e.g., improvement, stabilization, or slowing of disease progression for serum creatinine, calculated creatinine clearance, or leukocyte cystine concentration).

V. REFERENCES

1. Cystagon [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; January 2019.