

<b>Reference number</b>
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 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.; September 2017.