SPECIALTY GUIDELINE MANAGEMENT

PROCYSBI (cysteamine bitartrate delayed-release)

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
Procysbi is indicated for the treatment of nephropathic cystinosis in adults and pediatric patients 2 years of age and older.

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 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 experienced intolerance to prior therapy with Cystagon
3. Member is 2 years of age or older

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

IV. REFERENCES