# 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**


1. Procysbi [package insert]. Novato, CA: Raptor Pharmaceuticals Inc.; August 2015.
2. Ivanova E, De Leo MG, De Matteis MA, Levtchenko E. Cystinosis: clinical presentation, pathogenesis, and treatment. *Pediatr Endocrinol Rev.* 2014;12(1):176-184.