UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Procysbi

Program	Prior Authorization
Medication	Procysbi® (cysteamine bitartrate)
Pharmacy & Therapeutics Approval Date	5/2016
Effective Date	11/1/2016

1. Background:

Procysbi (cysteamine bitartrate) is a cystine-depleting agent indicated for the treatment of nephropathic cystinosis in adult and pediatric patients 2 years of age and older.

2. Coverage Criteria:

A. Initial Authorization

1. **Procysbi** will be approved based on **all** of the following criterion:

   a. Diagnosis of nephropathic cystinosis

   -AND-

   b. Age 6 years or older

   -AND-

   c. History of failure, contraindication or intolerance to Cystagon (cysteamine)

Authorization will be issued for 12 months.

B. Reauthorization

1. **Procysbi** will be approved based upon the following criterion:

   a. Documentation of positive clinical response to Procysbi therapy

Authorization will be issued for 12 months.

{Note: UnitedHealthcare generally does not consider frequency of dosing and/or lack of compliance to dosing regimens, an indication of medical necessity}

UnitedHealthcare Community Plan

3. References:

1. Procysbi [prescribing information]. Novato, CA: Raptor Pharmaceuticals Inc.; August 2015.
2. Gahl WA, Balog JZ, Kleta R. Nephropathic cystinosis in adults: natural history and effects of oral cysteamine therapy. Ann Intern Med. 2007 Aug 21;147(4):242-50..

Program	Program type – Prior Authorization
Change Control	
Date	Change
5/2016	New Program
6/2016	Updated policy template