

### Clinical Pharmacy Program Guidelines for Procysbi

Program	Prior Authorization
Medication	Procysbi (cysteamine bitartrate)
Issue Date	6/2014
Pharmacy and Therapeutics Approval Date	6/2017
Effective Date	8/2017

**1. Background:**

Procysbi 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:**

<p><b>A. <u>Initial Authorization</u></b></p> <p>1. <b>Procysbi</b> will be approved based on <b><u>all</u></b> of the following criteria:</p> <p style="margin-left: 40px;">a. Diagnosis of nephropathic cystinosis</p> <p style="text-align: center;">-AND-</p> <p style="margin-left: 40px;">b. Patient is 2 years of age or older</p> <p style="text-align: center;">-AND-</p> <p style="margin-left: 40px;">c. History of failure or intolerance to Cystagon (immediate-release cysteamine bitartrate)</p> <p><b>Note: UHC generally does not consider frequency of dosing and/or lack of compliance to dosing regimens, an indication of medical necessity</b></p> <p><b>Authorization will be issued for 12 months.</b></p> <p><b>B. <u>Reauthorization</u></b></p> <p>1. <b>Procysbi</b> will be approved based on the following criteria:</p> <p style="margin-left: 40px;">a. Documentation of positive clinical response to Procysbi therapy</p>
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**Authorization will be issued for 12 months.**

**3. References:**

1. Procysbi prescribing information. Lake Forest, IL: Horizon Pharma USA, Inc; March 2017.
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	Prior Authorization - Procysbi (cysteamine bitartrate)
<b>Change Control</b>	
Date	Change
6/2014	New Policy
10/2014	Changed language requiring previous trial of Cystagon and added a clarification that dosing and/or lack of compliance are not generally considered for medical necessity.
9/2016	Updated policy template and changed age requirement from 6 years old to 2 years old
6/2017	No changes to clinical criteria. Updated background and references.