UnitedHealthcare Community Plan

# Clinical Pharmacy Program Guidelines for Procysbi

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| Program | Prior Authorization |
| Medication | Procysbi (cysteamine bitartrate) |
| Markets in Scope | Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina |
| Issue Date | 6/2014 |
| Pharmacy and Therapeutics Approval Date | 6/2020 |
| Effective Date | 8/2020 |

## 1. Background:

Procysbi is a cystine-depleting agent indicated for the treatment of nephropathic cystinosis in adult and pediatric patients 1 year of age and older.

## 2. Coverage Criteria:

**A. Initial Authorization**

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

   a. Diagnosis of nephropathic cystinosis

   **-AND-**

   b. Patient is 1 year of age or older

   **-AND-**

   c. History of failure or intolerance to Cystagon (immediate-release cysteamine bitartrate)

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

**Authorization will be issued for 12 months.**

**B. Reauthorization**

1. **Procysbi** will be approved based on the following criteria:

a. Documentation of positive clinical response to Procysbi therapy

**Authorization will be issued for 12 months.**

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**


1. Procysbi [package insert]. Lake Forest, IL: Horizon Pharma USA, Inc.; February 2020.
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.


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| **Change Control** | |
| 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. |
| 6/2018 | Changed age requirement from 2 years old to 1 year old based on expanded indication. Updated references. |
| 6/2019 | Annual review. No changes to criteria. |
| 6/2020 | Annual review. Updated references. Added Additional Clinical Rules section. |