

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1081-13
Program	Prior Authorization/Notification
Medication	Procysbi® (cysteamine bitartrate)
P&T Approval Date	7/2013, 7/2014, 7/2015, 6/2016, 6/2017, 6/2018, 6/2019, 6/2020, 6/2021, 6/2022, 6/2023, 6/2024
Effective Date	9/1/2024

1. Background:

Procysbi (cysteamine bitartrate) is a cystine-depleting agent indicated for the treatment of nephropathic cystinosis in adult and pediatric patients 1 years of age and older.

2. Coverage Criteria^a:

<p>A. <u>Initial Authorization</u></p> <p>1. Procysbi will be approved based on the following criterion:</p> <p style="padding-left: 40px;">a. Diagnosis of nephropathic cystinosis</p> <p style="text-align: center;">Authorization will be issued for 12 months.</p> <p>B. <u>Reauthorization</u></p> <p>1. Procysbi will be approved based upon the following criterion:</p> <p style="padding-left: 40px;">a. Documentation of positive clinical response to Procysbi therapy</p> <p style="text-align: center;">Authorization will be issued for 12 months.</p> <p>^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</p>

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]. Deerfield, IL: Horizon Therapeutics USA, Inc.; February 2022.
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	
7/2013	New program.
7/2014	Annual review. No changes to the criteria.
10/2014	Modification to implementation date
7/2015	Annual review with no change to criteria.
6/2016	Annual review with no changes to criteria. Updated background and references.
6/2017	Annual review with no changes to criteria. Updated reference.
6/2018	Annual review with no changes to criteria. Updated reference.
6/2019	Annual review with no changes to criteria.
6/2020	Annual review with no changes to criteria. Updated reference.
6/2021	Annual review with no changes to criteria.
6/2022	Annual review with no changes to criteria. Updated reference.
6/2023	Annual review with no changes to criteria. Added state mandate footnote.
6/2024	Annual review with no changes to criteria.