

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1081-14
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, 6/2025
Effective Date	9/1/2025

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:

A. Initial Authorization

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

- a. Diagnosis of nephropathic cystinosis

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.

^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.

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.
6/2025	Annual review with no changes to criteria.