

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1282-7
Program	Prior Authorization/Notification
Medication	Samsca® (tolvaptan)
P&T Approval Date	6/2019, 6/2020, 6/2021, 6/2022, 6/2023, 6/2024, 6/2025
Effective Date	9/1/2025

1. Background:

Samsca is a selective vasopressin V₂-receptor antagonist indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH).¹

Limitations of Use:

- Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with Samsca.
- It has not been established that Samsca provides a symptomatic benefit to patients.

2. Coverage Criteria^a:

A. Hypervolemic or Euvolemic Hyponatremia

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

a. **One** of the following:

(1) Diagnosis of clinically significant euvolemic hyponatremia

-OR-

(2) Diagnosis of clinically significant hypervolemic hyponatremia

-AND-

b. Patient has not responded to fluid restriction

-AND-

c. Treatment has been initiated or re-initiated in a hospital setting prior to discharge

Authorization will be issued for 30 days.

^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. Samsca [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; April 2021.

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Change Control	
6/2019	New program.
6/2020	Annual review. No changes to criteria.
6/2021	Annual review. No changes to criteria. Updated background and references.
6/2022	Annual review. No changes to criteria. Updated background and references.
6/2023	Annual review with no changes to criteria. Added state mandate footnote.
6/2024	Annual review with no changes to criteria. Updated formatting of background.
6/2025	Annual review with no changes to criteria.