

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

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

**1. Background:**

Samsca is a selective vasopressin V<sub>2</sub>-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).<sup>1</sup>

*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<sup>a</sup>:**

**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.**

<sup>a</sup> 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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<b>Change Control</b>	
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.