UnitedHealthcare

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1282-5
Program	Prior Authorization/Notification
Medication	Samsca® (tolvaptan)
P&T Approval Date	6/2019, 6/2020, 6/2021, 6/2022, 6/2023
Effective Date	9/1/2023; Oxford only: 9/1/2023

1. Background:

Samsca is a selective vasopressin V_2-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.

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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.

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