

Clinical Pharmacy Program Guidelines for Samsca

Program	Prior Authorization
Medication	Samsca (tolvaptan)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Samsca is 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).

2. Coverage Criteria:

<p>A. <u>Hypervolemic or Euvolemic Hyponatremia</u></p> <p>1. Samsca will be approved based on <u>all</u> of the following:</p> <p style="padding-left: 40px;">a. <u>One</u> of the following:</p> <ul style="list-style-type: none"> • Diagnosis of clinically significant euvolemic hyponatremia • Diagnosis of clinically significant hypervolemic hyponatremia <p style="text-align: center;">-AND-</p> <p style="padding-left: 40px;">b. Patient has not responded to fluid restriction</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 40px;">c. Treatment has been initiated or re-initiated in a hospital setting prior to discharge</p> <p style="text-align: center;">Authorization will be issued for 30 days.</p>
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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]. Tokyo, Japan: Otsuka Pharmaceutical Co., Ltd.; June 2018.

Program	Prior Authorization –Samsca (tolvaptan)
Change Control	
Date	Change
9/2013	New guideline
12/2015	Annual review, no change
11/2016	Annual review, updated policy template
9/2017	Added requirement that patient has not responded to fluid restriction. Removed warning and precautions since this information is typically not included in policies. Updated references.
9/2018	Annual review. Updated references.
6/2019	Annual review. Revised authorization duration. Updated references.
6/2020	Annual review. Removed important limitations and black box warnings from background.