

Clinical Pharmacy Program Guidelines for Samsca

Program	Prior Authorization
Medication	Samsca (tolvaptan)
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	9/2017
Effective Date	11/2017

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). Important limitations: 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:

<p>A. <u>Authorization</u></p> <p>1. Samsca will be approved based on both of the following:</p> <p>a. One 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>b. Patient has not responded to fluid restriction</p> <p style="text-align: center;">-AND-</p> <p>c. Treatment has been initiated or re-initiated in a hospital setting prior to discharge</p> <p>Authorization will be issued for 1 month.</p>

3. References:

1. Samsca Prescribing Information. Otsuka America Pharmaceuticals, Inc., February 2014.
2. Ghali JK. Mechanisms, risks, and new treatment options for hyponatremia. *Cardiology*. 2008;11:147-157.

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.