Samsca (tolvaptan)

Policy Number: 5.01.544       Last Review: 06/2014
Origation: 06/2013            Next Review: 06/2015

Policy
BCBSKC will provide coverage for Samsca when it is determined to be medically necessary because the following criteria are met.

When Policy Topic is covered:
The use of Samsca may be considered medically necessary for the following:

Treatment of clinically significant hypervolemic and euvoletic hyponatremia (serum sodium of less than 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure, cirrhosis, and syndrome of inappropriate antidiuretic hormone (SIADH).

When Policy Topic is not covered:
The use of Samsca is considered investigational for all other indications.

Considerations
Samsca requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Hayes Medical Technology Directory, Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service
Samsca, a selective vasopressin V₂-receptor antagonist, is indicated for the treatment of clinically significant hypervolemic and euvoletic 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 (HF), cirrhosis, and syndrome of inappropriate antidiuretic hormone (SIADH). 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 raising serum sodium with Samsca provides a symptomatic benefit to patients. Samsca has a boxed warning that patients should be in a hospital for initiation and re-initiation of therapy to assess the therapeutic response. Too rapid a correction of hyponatremia can lead to osmotic demyelination causing dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriaparesis, seizures, coma, and death.

Rationale
Two trials (Study of Ascending Levels of Tolvaptan in Hyponatremia 1 and 2 [SALT-1 and SALT-2; n = 424]) demonstrated that Samsca increased serum sodium effectively in patients with euvoletic or hypervolemic hyponatremia that was due to many underlying causes (e.g., HF, liver cirrhosis, SIADH).²
² Patients (aged ≥ 18 years) received therapy for 30 days with Samsca or placebo, and were then followed for an additional 7 days after study withdrawal. Patients in the trial had a serum sodium < 135 mEq/L at study entry (baseline 129 mEq/L). In both trials, Samsca therapy led to a greater increase in serum sodium (P < 0.0001) compared with baseline at the measured endpoints at Day 4 and Day 30.
The effects of sustained serum sodium were demonstrated for up to 1 year in an open-label study.\(^1\) Another long-term analysis (the Safety and sodium Assessment of Long-term Tolvaptan With hyponatremia: A year-long, open-label Trial to gain Experience under Real-world conditions [SALTWATER]) showed that in 111 patients who received Samsca for approximately 1.9 years, increases in serum sodium were maintained with reasonable safety.\(^3\)

In a Phase III, prospective, multicenter, double-blind, placebo-controlled study 4,133 patients with worsening HF were randomized to Samsca or placebo as an adjunct to standard of care.\(^4^\) Patients received Samsca 30 mg once daily (n = 2,072) or placebo (n = 2,061) within 48 hours after hospital admission for a minimum of 60 days. The majority of patients were receiving standard HF medications including diuretics (96.8%), angiotensin-converting enzyme (ACE) inhibitors (84.2%), and beta-blockers (70.2%). Approximately 72% of patients (n = 2,906/4,030) had a serum sodium of > 137 mEq/L. During the trial, 22% of patients in the Samsca group and 21% in the placebo group discontinued the study medication permanently for reasons other than death.\(^4^\)\(^5\) Long-term Samsca treatment (mean duration of approximately 9 months of therapy) had no demonstrated effect, either favorable or unfavorable, on all-cause mortality or the combined endpoint of cardiovascular (CV) mortality or subsequent hospitalizations for worsening HF.\(^1^\)\(^4^\)\(^5\) During the trial, 537 patients given Samsca (25.9%) and 543 patients in the placebo group (26.3%) died (P = 0.68). The second of the two primary endpoints (death from CV causes or first hospitalization for HF) was reached by 871 patients given Samsca (42.0%) and 829 patients in the placebo group (40.2%) (P = 0.55).\(^4^\)\(^5\)

References:


Other References Utilized


Billing Coding/Physician Documentation Information

N/A Samsca is considered a pharmacy benefit.

Additional Policy Key Words

Policy Number: 5.01.544

Related Topics

N/A
Policy Implementation/Update Information

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<th>Date</th>
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<tbody>
<tr>
<td>06/2013</td>
<td>New Policy titled Samsca</td>
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<tr>
<td>06/2014</td>
<td>Reviewed – no changes made</td>
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This Medical Policy is designed for informational purposes only and is not an authorization, an explanation of benefits, or a contract. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there is any exclusion or other benefit limitations applicable to this service or supply. Medical technology is constantly changing and Blue Cross and Blue Shield of Kansas City reserves the right to review and revise medical policy. This information is proprietary and confidential and cannot be shared without the written permission of Blue Cross and Blue Shield of Kansas City.