Pharmacy Policy Bulletin

Title:	Tolvaptan (Samsca™)
Policy #:	Rx.01.89

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **tolvaptan (Samsca™)** as provided under the member's pharmacy benefit.

Description:

Hyponatremia is defined as a relative excess of water in relation to sodium. Treatment approaches depend on the duration, severity, and cause of hyponatremia.

Tolvaptan is a selective vasopressin V2 receptor antagonist. Tolvaptan antagonizes the effect of vasopressin and causes an increase in urine water excretion that results in an increase in free water clearance, a decrease in urine osmolality and a resulting increase in serum sodium concentrations.

Tolvaptan (Samsca) is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium < 125meq/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.

Policy:

Tolvaptan (Samsca™) is approved when there is a diagnosis of ALL of the following:

A. Member is 18 years of age or older
B. Clinically significant hypervolemic or euvolemic hyponatremia and ONE of the following:
    1. Serum sodium less than 125meq/L; or
    2. Serum sodium 125-134meq/L with symptoms (ie nausea, vomiting, headache, lethargy, confusion, etc)
C. Inadequate response or inability to tolerate therapies to control hyponatremia (ie fluid restriction, diuretics, demeclocycline, etc)

D. Prescriber is cardiologist, nephrologist, or endocrinologist

Black Box Warning:

INITIATE AND RE-INITIATE IN A HOSPITAL AND MONITOR SERUM SODIUM

Tolvaptan should be initiated and re-initiated in patients only in a hospital where serum sodium can be monitored closely.

Too rapid correction of hyponatremia (e.g., >12 mEq/L/24 hours) can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death. In susceptible patients, including those with severe malnutrition, alcoholism or advanced liver disease, slower rates of correction may be advisable.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Samsca (tolvaptan) [package insert]. Tokyo, Japan. Otsuka Pharmaceutical Co, Ltd. February 2014. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=5526617c-c7b9-4556-886d-729bbabbc566&type=display. Accessed February 15, 2017.

Sterns RH. Overview of the treatment of hyponatremia in adults. UpToDate. April 2015. Available at: https://www.uptodate.com/contents/overview-of-the-treatment-of-hyponatremia-in-adults?source=search_result&search=hyponatremia&selectedTitle=2~150#H25. Accessed February 15, 2017.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Samsca™	Tolvaptan

Cross References:

Policy Version Number:	7.00
P&T Approval Date:	January 12, 2017
Policy Effective Date:	March 01, 2017

Next Required Review Date: January 12, 2018