



## Prior Authorization Approval Criteria

### *Samsca (tolvaptan)*

<b>Generic name:</b>	Tolvaptan
<b>Brand name:</b>	Samsca
<b>Medication class:</b>	selective vasopressin antagonist
<b>FDA-approved uses:</b>	treatment of clinically significant hypervolemic and euvolemic hyponatremia, including patients with heart failure, cirrhosis, and Syndrome of Inappropriate Antidiuretic Hormone (SIADH).
<b>Available dosage forms:</b>	15mg and 30mg tablets
<b>Usual dose:</b>	Start at 15mg once daily. May be increased at intervals $\geq$ 24 hr to 30mg once daily, and to a maximum of 60mg once daily.
<b>Approximate cost:</b> (based on AWP 2009)	\$300.00/pill for both strengths. \$9,000-\$18,000/month.
<b>Duration of therapy:</b>	Until correction of hyponatremia and improvement in fluid balance and clinical status.

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must be initiated or re-initiated in a hospital.
- Will only be approved for 4 days at a time.

**Criteria for continuation of therapy:**

- Until correction of hyponatremia and improvement in fluid balance and clinical status.

**Caution:**

- Multiple drug interactions with drugs that affect CYP3A4 enzymes.

**Monitoring:**

- Serum sodium
- Volume status

**Contraindication:**

- Do not administer to patients requiring urgent intervention to raise serum sodium acutely.
- Do not use in patients who are unable to sense of to respond appropriately to thirst
- Do not use with in patients with hypovolemic hyponatremia
- Do not use with strong CYP 3A inhibitors
- Do not administer to patients who are anuric as no benefit is expected.

**Not approved if:**

- Samsca was not started in the hospital.

- Patient has any contraindications to the use of Samsca.

**Special considerations:**

- It has not been established that raising serum sodium with Samsca provides a symptomatic benefit to patients.

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 12/09/09