

# OAPI Patient Assistance Program for SAMSCA™ (tolvaptan)

For more information or to download additional forms, please visit [www.samsca.com](http://www.samsca.com).

## INDICATION

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, cirrhosis, 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 raising serum sodium with SAMSCA provides a symptomatic benefit to patients

## WARNING: INITIATE AND RE-INITIATE IN A HOSPITAL AND MONITOR SERUM SODIUM

- SAMSCA 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

Please see IMPORTANT SAFETY INFORMATION on page 4.

# ELIGIBILITY REQUIREMENTS

Otsuka America Pharmaceutical, Inc., the distributor and marketer of SAMSCA™ (tolvaptan), an orally administered selective vasopressin V<sub>2</sub>-receptor antagonist, is committed to providing access to this therapy through the OAPI Patient Assistance Program for SAMSCA. Through this program, eligible patients experiencing financial hardship who are uninsured will be able to maintain their hospital-initiated and re-initiated treatment with SAMSCA in an outpatient setting.

The OAPI Patient Assistance Program for SAMSCA is designed to assist patients who meet certain financial and other eligibility requirements. All applications submitted to the program will be evaluated using objective criteria, including:

- No insurance coverage such as: a private payer, Medicaid, Medicare (Medicare Part D), state-sponsored insurance, or pension coverage
- An income of ≤300% of federal poverty level
- Legal US residency

Persons in family	Maximum annual income		
	48 contiguous states and District of Columbia	Alaska	Hawaii
1	\$32,490	\$40,590	\$37,380
2	43,710	54,630	50,280
3	54,930	68,670	63,180
4	66,150	82,710	76,080
5	77,370	96,750	88,980
6	88,590	110,790	101,880
7	99,810	124,830	114,780
8*	111,030	138,870	127,680

\*For families with more than 8 persons in the 48 contiguous states and the District of Columbia, add \$11,220 for each additional person; for Alaska, add \$14,040; for Hawaii, add \$12,900.

Source: Annual update of the HHS poverty guidelines. *Fed Regist.* 2009;74(14):4199-4201.

Please see IMPORTANT SAFETY INFORMATION on page 4.

# APPLYING FOR ASSISTANCE

The OAPI Patient Assistance Program for SAMSCA application is simple to complete. All portions of the application and supporting documentation must be answered and submitted.

There are 3 steps to follow in completing the application process:

**1. Complete patient portion:**

Fill in the patient information, insurance information, and financial assessment. Patient or guardian must sign application.

**2. Complete physician portion:**

Fill in the physician information, prescription information, and physician services. Physician must sign application.

**3. Fax completed application to 1-866-565-7793:**

Submit the application to the OAPI Patient Assistance Program for SAMSCA along with copies of all required documentation so that your application can be reviewed promptly.

Once the application is received, we can determine the patient's eligibility for the program:

- A program counselor will evaluate the application using preestablished criteria
- If the application is approved, the patient is eligible for assistance for a period of up to 1 year
- A program counselor will arrange for a maximum supply of 1 month (no refills) of SAMSCA per prescription to be sent to the patient's home
- **Each month, a prescription and certification will be required by the physician to confirm that therapy with SAMSCA and assistance should continue. Additionally, verification is required to confirm that there has been no interruption in therapy with SAMSCA, which would necessitate re-initiation in a hospital**

Patients and physicians may obtain application assistance or additional information by contacting their representative for SAMSCA or the OAPI Patient Assistance Program at 1-866-758-7069, Monday through Friday, 8:30 AM to 8:00 PM Eastern Time. Additional application forms can be downloaded from [www.samsca.com](http://www.samsca.com).

**Note:**

Otsuka America Pharmaceutical, Inc., reserves the right to modify or discontinue the OAPI Patient Assistance Program for SAMSCA or terminate assistance at any time. Third-party reimbursement is affected by a range of factors; therefore, the Program cannot guarantee coverage. Program administrators reserve the right to refer applicants to other sources of insurance before being considered for the OAPI Patient Assistance Program for SAMSCA.

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## IMPORTANT SAFETY INFORMATION FOR SAMSCA™ (tolvaptan)

**SAMSCA 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.**

**SAMSCA is contraindicated in the following conditions:** Urgent need to raise serum sodium acutely, inability of the patient to sense or appropriately respond to thirst, hypovolemic hyponatremia, concomitant use of strong CYP 3A inhibitors, anuric patients

- **Too Rapid Correction of Serum Sodium Can Cause Serious Neurologic Sequelae** – During initiation and after titration monitor patients to assess serum sodium concentrations and neurologic status. Subjects with SIADH or very low baseline serum sodium concentrations may be at greater risk for too-rapid correction of serum sodium. In patients receiving SAMSCA who develop too rapid a rise in serum sodium, discontinue or interrupt treatment with SAMSCA and consider administration of hypotonic fluid. Fluid restriction during the first 24 hours with SAMSCA may increase the likelihood of overly-rapid correction of serum sodium, and should generally be avoided.
  - **Gastrointestinal Bleeding in Patients with Cirrhosis** – Used only when the need to treat outweighs this risk
  - **Dehydration and Hypovolemia** – In patients who develop medically significant signs or symptoms of hypovolemia, discontinuation is recommended. Dehydration and hypovolemia can occur, especially in potentially volume-depleted patients receiving diuretics or those who are fluid restricted.
  - **Co-administration with Hypertonic Saline** – Not recommended
  - **Other Drugs Affecting Exposure to SAMSCA**
    - **CYP 3A Inhibitors** – Do not use with strong inhibitors of CYP 3A; avoid concomitant use with moderate CYP 3A inhibitors
    - **CYP 3A Inducers** – Avoid concomitant use with CYP 3A inducers. If co-administered, the dose of SAMSCA may need to be increased
    - **P-gp Inhibitors** – The dose of SAMSCA may have to be reduced if co-administered with P-gp inhibitors
  - **Hyperkalemia or Drugs that Increase Serum Potassium** – Monitor serum potassium levels in patients with a serum potassium >5 mEq/L and in patients receiving drugs known to increase serum potassium levels
- Pregnancy and Nursing Mothers** – SAMSCA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Because many drugs are excreted into human milk and because of the potential for serious adverse reactions in nursing infants from SAMSCA, a decision should be made to discontinue nursing or SAMSCA, taking into consideration the importance of SAMSCA to the mother.
- Commonly observed adverse reactions** – (incidence  $\geq$ 5% more than placebo): thirst (16% vs 5%), dry mouth (13% vs 4%), asthenia (9% vs 4%), constipation (7% vs 2%), pollakiuria or polyuria (11% vs 3%) and hyperglycemia (6% vs 1%)

Please see accompanying FULL PRESCRIBING INFORMATION, including **Boxed WARNING**.



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Otsuka America Pharmaceutical, Inc.