Prescription Referral Template

Specialty Pharmacy Network for SAMSCA® (tolvaptan)

This resource is being provided for your consideration when creating a process for referring prescriptions for SAMSCA to a pharmacy in Otsuka's Specialty Pharmacy Network for SAMSCA.

The information captured within this resource reflects data commonly required by specialty pharmacies to dispense a prescription for SAMSCA. In some cases, there may be additional information required. Please expect each pharmacy to maintain an open line of communication until prescriptions are dispensed.

This resource is being provided for informational purposes only and is not all inclusive of specialty pharmacy requirements, insurance plan requirements or requirements of a Covered Entity under the Health Insurance Portability and Accountability Act of 1996 and other state law requirements. Use of this resource is not a guarantee that coverage and reimbursement will result in any particular case. Providers should consult with their payers for all relevant coverage, coding, and reimbursement requirements. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. This resource is not intended as legal advice or a substitute for a provider's independent professional judgment.

Prescription Referral Template

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Date/time of referral: _____ Referral received by: _____

PATIENT INFORMATION

☐ Attach copy of demographic/face sheet OR complete below

Last name: _____ First name: _____ MI: ____

Address: _____ City: _____ State: _____ ZIP: _____

SSN (optional): ____– ____– ____ DOB: ____/____/____ Gender: _____

Preferred method of contact: Call patient ☐ Call legal authorized representative ☐ Best time to call: AM ☐/PM ☐

Patient phone: (___) - ___- _____ Preferred language: _____

Legal authorized representative (name): _____ Relationship: _____

Representative phone: (___) - ___ - _____

PATIENT INSURANCE INFORMATION

☐ Attach all insurance and prescription cards OR complete below

Medical Card

Payer Name: _____ Plan Name: _____

Phone: (___) - ___ - _____ Member ID: _____

Group #: _____ Policyholder DOB: _____

Policyholder Name: _____

Prescription Card

Member ID: _____ BIN #: _____ PCN #: _____

PRESCRIBER AND HOSPITAL INFORMATION

Prescriber name: _____ Specialty: Nephrology ☐ Cardiology ☐ Oncology ☐ Other: _____

State license #: _____ TIN #: _____

NPI #: _____ Direct phone: (___) - ___- _____ Fax: (___) - ___- _____

Address: _____ City: _____ State: _____ ZIP: _____

Hospital contact name: _____ Site name: _____

Preferred method of contact: Phone ☐ Fax ☐ Mobile (text messaging) ☐

Direct phone: (___) - ___- _____ Cell phone: (___) - ___ - _____ Fax: (___) - ___- _____ Alt. phone: (___) - ___ - _____

Site name: _____

Address: _____ City: _____ State: _____ ZIP: _____

DIAGNOSIS AND TREATMENT DETAILS

Diagnosis code(s) (please check all that apply):

☐ E87.1: Hypo-osmolality and hyponatremia

☐ E22.2: Syndrome of inappropriate secretion of antidiuretic hormone (SIADH)

☐ Other: _____

COMMON PRIOR AUTHORIZATION QUESTIONS:

Has the patient failed to respond to fluid restriction?

What was the patient's serum sodium level (mEq/L) prior to SAMSCA initiation?

Has the patient been admitted or readmitted to the hospital in the last 30 to 90 days?

Inpatient treatment initiation date: _____

Anticipated discharge date: _____

Total quantity dispensed since hospital admission: _____

PRESCRIPTION

Please e-prescribe, attach a prescription, or complete below:

Rx date: ___/___/___ Strength: 15 mg ☐ 30 mg ☐ Sig: Take ____ by mouth once a day Qty: _____ (partial dispense permissible) Refills: ____

I certify that therapy with SAMSCA® (tolvaptan) is medically necessary for this patient and that I have reviewed the current SAMSCA Prescribing Information.

Prescriber name (printed) _____

Prescriber signature _____ Date _____

Rx REFERRAL TO NETWORK PHARMACY

Has prescription already been sent to another network pharmacy? Yes ☐ No ☐ If yes, pharmacy name: _____

If no, please select a pharmacy: 15Rx Pharmacy (Texas only) ☐ Accredo ☐ BriovaRx ☐ Cigna Specialty Pharmacy ☐

CVS Specialty Pharmacy ☐ DirectRx Pharmacy ☐ Premier Pharmacy Services ☐ Albertsons Specialty Care/Safeway Specialty Pharmacy ☐

Walgreens Specialty Pharmacy ☐ Walgreens Health System Pharmacy (local): _____

Please see IMPORTANT SAFETY INFORMATION on reverse.

Protected Health Information - Classified as: _____

INDICATION and IMPORTANT SAFETY INFORMATION for SAMSCA® (tolvaptan)

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 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

IMPORTANT SAFETY INFORMATION:

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**

WARNING: NOT FOR USE FOR AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD)

- **Because of the risk of hepatoxicity, tolvaptan should not be used for ADPKD outside of the FDA-approved REMS.**

SAMSCA is contraindicated in the following conditions:

- — Use in patients with Autosomal Dominant Polycystic Kidney Disease (ADPKD) outside of FDA-approved REMS
- — 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
- — Hypersensitivity (e.g. anaphylactic shock, rash generalized) to tolvaptan or its components

- **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. Co-administration of diuretics also increases the risk of too rapid correction of serum sodium and such patients should undergo close monitoring of serum sodium.
- **Liver Injury:** Tolvaptan can cause serious and potentially fatal liver injury. In clinical trials, cases of serious liver injury have been attributed to chronically administered tolvaptan in patients with ADPKD. Liver failure requiring transplantation has been reported in postmarketing experience with tolvaptan in ADPKD. Limit duration of therapy with SAMSCA to 30 days. Avoid use in patients with underlying liver disease, including cirrhosis, because the ability to recover may be impaired.
- **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

Adverse Reactions: The most common adverse reactions (SAMSCA incidence ≥5% more than placebo, respectively): 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%)

Gastrointestinal Bleeding in Patients with Cirrhosis: In patients with cirrhosis in the hyponatremia trials, GI bleeding was reported in 10% of tolvaptan-treated patients vs 2% for placebo

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

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch)

Please see FULL PRESCRIBING INFORMATION, including BOXED WARNING.

Manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan.
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Otsuka America Pharmaceutical, Inc.