COVER SHEET

This page is provided as a guide / fax cover sheet and is not required for enrollment

FAX OR MAIL COMPLETED FORMS

Fax: 1 (866) 565-7793 **Questions?** Call 1 (866) 758-7069

Need help completing the form? Visit http://ASSURE.com/HCP/Samsca for an instruction guide

IMPORTANT INSTRUCTIONS

- **Please ensure that all necessary information is provided (fields in gray are optional)**
- **You may complete each section or provide copies of face sheets, insurance cards and prescriptions with the necessary information**
- **If the patient is uninsured and would like to be reviewed for Patient Assistance, please complete the PAP Enrollment Form (last two pages of this file)**

Page 1: Prescriber and hospital information

- ☐ Identify preferred method of contact (i.e., phone call or fax) for the hospital contact
- ☐ Opt-in for text updates on patient status in enrollment process
- ☐ Provide required treatment information and complete or attach outpatient prescription*
- ☐ Prescriber signature required

Page 2: Patient information and authorization

- ☐ Verify patient's shipping address (this address is where outpatient product will be sent) – please note that we cannot ship to PO Box addresses
- ☐ Include both insurance and prescription coverage if available; if patient has more than one insurance plan, please include both
- ☐ Please present Section 5 (Patient Authorization) to patient

Note on insurance coverage:

- Patients with **commercial** insurance only are eligible for co-pay savings
- Patients with **Medicare Part D** are not eligible for co-pay savings but may be eligible for other forms of ASSURE coverage support (e.g., appeals and letters of medical necessity)

**The purpose of the prescription section of the enrollment form is to evaluate eligibility for financial support information and assistance. It also serves as an actionable prescription for the Patient Assistance Program, and for dispenses of bridge product where applicable.*

Please **CLICK HERE** for Full Prescribing Information for Samsca® (tolvaptan), including **Boxed WARNING**.
Please see the Indication and Important Safety Information on page 3.

Patient Enrollment Form for SAMSCA® (tolvaptan)

ASSURE™

FAX COMPLETED FORMS TO 1 (866) 565-7793 | Phone: 1 (866) 758-7069

1. PRESCRIBER & HOSPITAL INFORMATION (PLEASE PROVIDE A HOSPITAL CONTACT)

Hospital contact person: Hospital:

Preferred method of contact:
☐ Phone call ☐ Fax ☐ Send me text updates about patient enrollment status at this number: ( ) -

Hospital contact's phone: ( ) - Fax: ( ) - Email:

Address: City: State: Zip:

Prescriber: Specialty:

Tax ID #: License #: State Licensed: Phone: ( ) -

☐ Send me text updates about patient enrollment status at this number: ( ) -

2. PRESCRIPTION INFORMATION

Support will only be provided for patients whose prescribed usage is in a manner that is consistent with the approved labeling. Avoid use in patients with underlying liver disease, including cirrhosis, because the ability to recover from injury may be impaired. Limit duration of therapy to 30 days.

ATTACH PRESCRIPTION OR COMPLETE

Prescribed dose of SAMSCA® (tolvaptan): ☐ 15 mg tablets ☐ 30 mg tablets

Dispense _____ (partial dispense permissible) Sig: Take _____ tablets daily

REQUIRED INFORMATION

Diagnosis Code(s):
(please check all that apply)
☐ ICD-9 276.1 / ICD-10 E87.1
☐ ICD-9 253.6 / ICD-10 E22.2
☐ Other _____

Inpatient treatment initiation date: _____ Anticipated discharge date: _____

Total number of dispenses since hospital admission: _____

I certify that the treatment listed above is and will be medically necessary based on my best professional judgment and that the information provided in this form is complete and accurate to the best of my knowledge. I also certify that I have obtained patient consent for the disclosure of protected health information (PHI) as required by the Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA), and any other legally required consents of the patient (or the patient's legal representative) for the release of the patient's information to the ASSURE Program (the "Program") and Otsuka America Pharmaceutical, Inc. and/or its representatives or agents (collectively, OAPI), as may be necessary for the patient's participation in the Program and for the Program and OAPI to use and disclose such information as necessary to provide reimbursement support and other related services to me and my patient in connection with the patient's therapy of SAMSCA® (tolvaptan). I attest that I am not on the HHS/OIG list of Excluded Individuals and that I am authorized under State law to prescribe and dispense the requested medication. I authorize and appoint the Program and OAPI to convey on my behalf any prescription information delivered to the Program to the dispensing pharmacy chosen by or for the patient. I understand that the Program and OAPI will use and disclose this information only in connection with the Program, including but not limited to performing a preliminary verification of the patient's insurance coverage for SAMSCA® (tolvaptan) and triage to OAPI's Patient Assistance Program ("PAP") if applicable, and as otherwise required or permitted by law. I further certify that (a) any service provided through the Program on behalf of any patient is not made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use SAMSCA® (tolvaptan) or any other OAPI product or service for anyone, and (b) my decision to prescribe SAMSCA® (tolvaptan) was based on my determination of medical necessity as set forth herein. I agree that the Program and OAPI may contact me for additional information relating to the Program or SAMSCA® (tolvaptan), including but not limited via email, fax and telephone. I understand that OAPI reserves the right, at any time and without notice, to modify or discontinue the Program. I understand that completing this enrollment form does not ensure that the patient will obtain insurance coverage or reimbursement for my prescription, and that any support provided through the Program are provided for information purposes only and represent no statement, promise or guarantee by the Program or OAPI. I agree that in no event shall OAPI be liable for any damages resulting from or relating to the Program. I am directing the retail pharmacy selected by my patient to administer the pharmaceutical product I have indicated.

Sign Here ✖

Prescriber's Signature (required) Printed Name Date

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Patient Enrollment Form for SAMSCA® (tolvaptan)

ASSURE™

FAX COMPLETED FORMS TO 1 (866) 565-7793 | Phone: 1 (866) 758-7069

Information on this page can often be found on patient face sheets and insurance card(s). Copies of these documents are accepted in lieu of filling out these sections. Please ask patient to read Section 5 and sign, if applicable.

3. PATIENT INFORMATION

First: MI: Last: Phone: ( ) -

Gender: ☐ M ☐ F DOB: SSN: Cell: ( ) -

Address: City: State: Zip:

Shipping Address, if different from above (no PO Boxes):

City: State: Zip:

4. PATIENT INSURANCE INFORMATION

ATTACH A COPY OF BOTH SIDES OF THE PATIENT'S INSURANCE CARD(S) OR COMPLETE BELOW

Primary Insurance

Plan Name: Policy #: Group #:

Policy Holder DOB: Policy Holder (or relationship): Insurance Phone: ( ) -

Primary Prescription Plan (IF PATIENT HAS ADDITIONAL PRESCRIPTION COVERAGE, PLEASE COMPLETE)

Plan Name: Policy #: Group #:

Policy Holder DOB: Policy Holder (or relationship): Insurance Phone: ( ) -

BIN: PCN:

Secondary Insurance

Plan Name: Policy #: Group #:

Policy Holder DOB: Policy Holder (or relationship): Insurance Phone: ( ) -

Secondary Prescription Plan

Plan Name: Policy #: Group #:

Policy Holder DOB: Policy Holder (or relationship): Insurance Phone: ( ) -

BIN: PCN:

5. PATIENT AUTHORIZATION

I authorize my healthcare provider, health insurer, pharmacist and other relevant third parties to disclose to Otsuka America Pharmaceutical, Inc. ("OAPI") and/or its agents (collectively, OAPI), and OAPI to use, my protected health information, including but not limited to insurance information, diagnosis, prescriptions and my city and state (together my "Protected Health Information") for purposes of internal data collection and analytic efforts. I understand that I can stop future sharing of my Protected Health Information for data collection and analytics purposes at any time by calling 1 (866) 758-7069 or by mailing a signed written statement of my revocation to PO Box 220750, Charlotte NC 28222-0750. I understand that revoking this authorization will prohibit disclosures after the date revocation is received, except to the extent that action has already been taken in reliance on this authorization.

I understand that:

- This authorization is entirely optional. I may decline to provide this authorization and still participate in the Otsuka Patient Assistance Program. My healthcare providers will not condition my medical treatment on my agreement to provide this authorization.
- This authorization will continue indefinitely until I revoke it as described above.
- Once my Protected Health Information is released based on this authorization, Federal and State privacy laws may not prevent the entities described above from re-disclosing my Protected Health Information, although they have agreed to only use or disclose information received for purposes described in this authorization or as otherwise permitted or required by law.
- I can request a copy of this authorization.

Sign Here ✖

Patient or Legal Authorized Representative's signature Year of Birth Date

Printed Name Relationship to Patient

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Please see the Indication and Important Safety Information on page 3.

Patient Enrollment Form for SAMSCA® (tolvaptan)

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DIAGNOSIS CODE DESCRIPTIONS

ICD-9 Code	Description	ICD-10 Code	Description
276.1	Hyposmolality and/or hyponatremia	E87.1	Hypo-osmolality and hyponatremia
253.6	Other disorders of neurohypophysis, i.e., syndrome of inappropriate antidiuretic hormone (SIADH)	E22.2	Syndrome of inappropriate secretion of antidiuretic hormone (SIADH)

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

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
- 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

- **Liver Injury** – SAMSCA can cause serious and potentially fatal liver injury. In a placebo-controlled and open-label extension study of chronically administered tolvaptan in patients with autosomal dominant polycystic kidney disease (ADPKD), cases of serious liver injury attributed to tolvaptan were observed. Avoid use in patients with underlying liver disease, including cirrhosis, because the ability to recover may be impaired. Limit duration of therapy with SAMSCA to 30 days. ***SAMSCA is not approved for use in ADPKD***

- **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

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

Please **CLICK HERE** for Full Prescribing Information for SAMSCA® (tolvaptan), including **Boxed WARNING.**

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COVER SHEET

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FAX OR MAIL COMPLETED FORMS

Fax: 1 (844) 727-6274

Questions? Call Otuska PAP at 1 (855) 727-6274

INSTRUCTIONS FOR PAP COMPLETION

☐ **Complete PATIENT INSURANCE INFORMATION**

☐ **Patient or Legal Authorized Representative's signature is required**

☐ **Please select income verification option(s) and attach one of the following acceptable forms of documentation if opting to submit income verification:**

- Copy of W-2 or most recently filed U.S. Income Tax Return, (IRS Form 1040, 1040A, 1040EZ, 1040NR or 1040PR), OR
- Copy of most recent pay stub plus most recently filed US Income Tax Return, OR
- Copy of transcript received through submission of IRS 4506-T (request for transcript form is not accepted), OR
- Copy of most recent Social Security/Disability monthly check, Award Letter, Benefit Statement or 1099, OR
- Copy of Unemployment Determination letter

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Patient Assistance Program Enrollment Form for SAMSCA® (tolvaptan)

ASSURE™

FAX COMPLETED FORMS TO 1 (844) 727-6274 | Phone: 1 (855) 727-6274

1. PATIENT INSURANCE INFORMATION

First: MI: Last: Phone: ( ) -

Gender: ☐ M ☐ F DOB: SSN: Cell: ( ) -

Does the patient have insurance or any prescription drug coverage?	☐ Yes	☐ No
Is the patient enrolled in Medicare, Medicaid, VA, or TRICARE?	☐ Yes	☐ No
If no to above, has patient applied for Medicare, Medicaid, VA, or TRICARE?	☐ Yes	☐ No
Is patient a United States citizen or resident?	☐ Yes	☐ No

Patient's annual household income $ _____ Household size, including patient: _____

(See approved forms of income documentation on cover sheet)

2. CERTIFICATION AND AUTHORIZATION TO DISCLOSE INFORMATION

The patient, or the patient's authorized representative, MUST sign this form to receive product at no cost from the Otsuka Patient Assistance Program ("PAP"). Before signing, you, the patient or an authorized representative, should review, understand, and agree to the terms of this authorization and release. If you are an authorized representative signing for the patient, please indicate your relationship to the patient.

I verify that the information provided on this form is true and correct.

I will immediately inform the Otsuka PAP and my healthcare provider if my income or insurance status changes while I am receiving help from the PAP.

I authorize my healthcare provider, health insurer, pharmacist and other relevant third parties to disclose to Otsuka America Pharmaceutical, Inc. ("OAPI") and/or its agents (collectively, OAPI), and OAPI to use, my protected health information, including but not limited to insurance information, diagnosis, prescriptions and my city and state (together my "Protected Health Information") for the purposes of administering the program. This includes investigating and resolving coverage, coding, or reimbursement inquiries, administering the Otsuka PAP, coordinating the delivery of product for my treatment, and determining if I am eligible for health insurance coverage or other funds.

I understand that:

- Application to the Otsuka PAP does not guarantee assistance.
- Participation in the Otsuka PAP is subject to approval under program guidelines.
- Approval is for a limited period.
- Periodic re-application is required for continued participation.
- My healthcare providers will not condition my medical treatment on my agreement to sign this Patient Authorization and Release.
- Once information about me is released based on this authorization, Federal and State privacy laws may not prevent the entities described above from re-disclosing my information, although they have agreed to only use or disclose information received for the purposes described in this authorization or as otherwise permitted or required by law.
- This authorization will remain in effect for one (1) year unless revoked earlier.
- I can cancel this authorization at any time by faxing a signed written statement of my cancellation to 1 (844) 727-6274 (1-844-PAP-OAPI), but this would end my eligibility to participate in the Otsuka PAP. Canceling this authorization will prohibit disclosures after the date written revocation is received, but not action that has already been taken by relying on this authorization. This means that, after I revoke this authorization, my information may be disclosed among OAPI and companies that help OAPI administer the programs in order to maintain records of my participation, but it will not be otherwise disclosed or used without my written consent.
- OAPI reserves the right at any time and without notice to modify or change eligibility criteria, or modify or discontinue the Otsuka PAP.
- I can request a copy of this form.

I authorize my insurer, doctor, healthcare provider, and pharmacist to:

- Release information about my prescribed medications and medical condition requested by OAPI;
- Disclose any information obtained from the sources listed above to third parties if required or otherwise permitted by law.

PLEASE SELECT INCOME VERIFICATION OPTION(S)

☐ Use attached income documentation (acceptable forms of income documentation listed on cover sheet).

☐ By checking this box, I authorize OAPI, their agents, and the third party contractors or their service providers authorized to administer the program to use my social security number and/or additional demographic information to access my credit information and information derived from public and other sources to estimate my income in conjunction with the eligibility determination process. I understand that I will be asked to submit an acceptable form of income documentation if the Otsuka PAP is unable to determine my financial eligibility based on my credit information.

Sign Here ✖

Patient or Legal Authorized Representative's signature Year of Birth Date

Printed Name Relationship to Patient

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