OTSUKA PATIENT ASSISTANCE FOUNDATION, INC.
PO Box 4530, Chesterfield, MO 63006
PHONE: 1-855-727-6274; FAX: 1-844-727-6274
HOURS: Monday-Friday 8am-8pm ET

SAMSCA® (tolvaptan) MEDICAL NECESSITY FORM

Today's Date (mm/dd/yyyy): _____

BOTH pages of this form must be completed in its entirety and submitted to the Otsuka Patient Assistance Foundation, Inc. (OPAF) every month by the prescribing provider for special exception continuous treatment. Prescription is valid for ONLY 30 days per the requirements of SAMSCA.

Please fax both pages of this form and a prescription to 1-844-727-6274.

PATIENT INFORMATION:

First Name: _____ Last Name: _____ MI:____

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

Patient Phone Number: * _____ (Required to schedule product shipment)

Patient's Date of Birth (mm/dd/yyyy): _____ ☐ Ship to Patient ☐ Ship to Provider

There is a request for the above referenced patient to receive a shipment of SAMSCA® (tolvaptan) free of charge from Otsuka Patient Assistance Foundation, Inc. (OPAF).

PRESCRIBER INFORMATION:

Prescriber Name: _____

State License#: _____ NPI#: _____

Address: _____ City: _____ State: _____ Zip: _____

Prescriber Phone: _____ Prescriber Fax: _____

MEDICAL/PRESCRIPTION INFORMATION: (For states with specific prescription requirements, please follow state regulations as required)

Diagnosis: _____

Dose of SAMSCA: (Check one) ☐ 30mg ☐ 15mg (Check one) ☐ QD ☐ BID

Quantity: _____(SAMSCA is indicated for no more than 30 Days Supply)

Date of Hospital Admission (mm/dd/yyyy): _____Date of Hospital discharge or expected discharge (mm/dd/yyyy): _____

Dosage while in Hospital: (Check one) ☐ 30mg ☐ 15mg Dosing frequency: _____

Number of SAMSCA tablets administered during hospital stay: _____

Number of SAMSCA tablets dispensed at hospital discharge: _____

I appoint the Otsuka Patient Assistance Foundation (hereafter, referred to as OPAF) to convey this prescription to the dispensing pharmacy. I certify that therapy with the above-mentioned product is medically necessary for this patient, and I have reviewed the current Prescribing Information for the prescribed product. I attest that I am not on the HHS/OIG List of Excluded Individuals and Entities and that I am presently authorized under state law to prescribe this medication. I authorize and appoint OPAF to convey on my behalf any prescription information delivered to the dispensing pharmacy. For the purposes of transmitting this prescription, I authorize OPAF and its affiliates as my agent for these limited purposes to forward this prescription electronically, or via fax, or via mail to the dispensing pharmacy. I certify that any medication received will be used only for the patient named on this application and will not be offered for sale, trade, or barter. I acknowledge that OPAF is a free goods, non-profit program that assists patients that have been approved for assistance by meeting specific criteria. I acknowledge, that at any time, I can change or withdraw this prescription on the patient's behalf due to the medical needs of the patient by calling 1-855-727-6274 or by sending a written notice to OPAF at Otsuka Patient Assistance Foundation Inc., PO Box 4530, Chesterfield, MO 63006. I understand that OPAF may revise, change, or terminate programs at any time.

☐ **Dispense as written**

Licensed Prescriber's Signature: Sign here _____ **Date:** (mm/dd/yyyy):_____

Samsca (tolvaptan)

Please see FULL PRESCRIBING INFORMATION including **BOXED WARNING** and MEDICATION GUIDE for SAMSCA®(tolvaptan) tablets at www.samsca.com .

 Confidential-Protected Health Information August 2023 PAUS23EBB0014

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Otsuka PATIENT ASSISTANCE FOUNDATION

MEDICAL CERTIFICATION

I certify that I am aware SAMSCA® (tolvaptan) may cause liver injury and that the full Prescribing Information states that SAMSCA should not be administered for more than 30 days to minimize the risk of liver injury. I am aware that tolvaptan can cause serious and potentially fatal liver injury. In placebo-controlled studies and an open-label extension study of chronically administered tolvaptan in patients with Autosomal Dominant Polycystic Kidney Disease (ADPKD), cases of serious liver injury have been attributed to tolvaptan, generally occurring during the first 18 months of therapy, were observed.

In post marketing experience with tolvaptan in ADPKD, acute injury resulting in liver failure requiring liver transplantation has been reported. **Because of the risk of hepatotoxicity, tolvaptan should not be used for ADPKD outside of the FDA-approved risk evaluation and mitigation strategy (REMS).** Avoid use in patients with underlying liver disease, including cirrhosis, because the ability to recover may be impaired.

I have considered therapeutic alternatives. I have advised my patient that SAMSCA can cause liver problems including life-threatening liver failure. I have advised my patient to talk to me if signs of liver injury appear or worsen, including loss of appetite, nausea, vomiting, fever, feeling unwell, unusual tiredness, itching, yellowing of the skin or the whites of the eyes (jaundice), unusual darkening of the urine, or right upper stomach area pain or discomfort. I have reviewed the Medication Guide with the patient and informed the patient that the full Prescribing Information states that SAMSCA should not be taken more than 30 days to minimize the risk of liver injury.

Fluid restriction during the first 24 hours of therapy 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.

As with any serious adverse event, I understand that I should report cases of hepatic injury or any serious adverse event to Otsuka by calling (800) 438-9927. Alternatively, I may report this information to FDA's MedWatch reporting system by phone (1-800-FDA-1088), by facsimile (1-800-FDA-0178), or https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm. Reports of serious adverse events can also be mailed using the MedWatch form FDA 3500 to the Medical Products Reporting Program, 5600 Fishers Lane, Rockville, Maryland 20852-9787.

I agree to the guidelines established by Otsuka America Pharmaceutical, Inc. Neither I nor my patient will seek payment or accept reimbursement from any third-party payer, including any state, federal, or private entity, or other insurance plans, such as Medicare, Medicaid, Medigap, VA, DOD or TriCare.

_____

Licensed Prescriber Signature

_____

Licensed Prescriber State License Number

_____

Date Signed (mm/dd/yyyy)

Please fax BOTH pages of this form and a prescription to 1-844-727-6274. If you need additional information about SAMSCA, please contact Otsuka Medical Affairs toll-free at 1-800-441-6763 or visit www.samsca.com.

Samsca (tolvaptan)

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