OTSUKA PATIENT ASSISTANCE FOUNDATION, INC.
PO Box 501878, San Diego, CA 92150-1878
PHONE: 1-855-727-6274 **FAX**: 1-844-727-6274
HOURS: Monday-Friday 8am-8pm ET

Otsuka
OTSUKA PATIENT ASSISTANCE FOUNDATION

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#: _____

Tax ID#: _____ NPI#: _____ DEA#: _____

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 dispensed at hospital discharge: _____

Licensed Prescriber Signature: Sign Here _____ **Date:** _____

Samsca® (tolvaptan)

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

OTSUKA PATIENT ASSISTANCE FOUNDATION, INC.
PO Box 3640, Gaithersburg, MD 20885-3640
PHONE: 1-855-727-6274 **FAX**: 1-844-727-6274
HOURS: Monday-Friday 8am-8pm EDT

Otsuka
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)

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