

## Tolvaptan (SAMSCA) Criteria for Use September 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

### Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive tolvaptan (SAMSCA):

- Use for autosomal dominant polycystic kidney disease (ADPKD)\*
- Underlying liver disease including cirrhosis
- Unable to sense or respond to thirst
- Hypovolemic hyponatremia
- Urgent need to raise serum sodium acutely
- Anuria
- Strong CYP 3A inhibitors (e.g., ketoconazole, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir, nefazodone, clarithromycin, and telithromycin) or moderate CYP 3A inhibitors (e.g., erythromycin, fluconazole, aprepitant, diltiazem, and verapamil)

\* SAMSCA is not FDA approved for ADPKD. Use the JYNARQUE tolvaptan product for the treatment of ADPKD. JYNARQUE is restricted to an FDA Risk Evaluation and Mitigation Strategy (REMS) (See PBM JYNARQUE CFU) which requires regular liver function monitoring due to the risk for hepatotoxicity.

### Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria:

- Care provided by a VA / VA Community Care endocrinologist, nephrologist, or other locally designated expert
- Diagnosis of clinically significant hypervolemic or euvolemic hyponatremia (serum sodium less than 125 mEq/L or less marked hyponatremia that is symptomatic and unresponsive to fluid restriction)
- Initiation and re-initiation conducted in a hospital setting (for close serum sodium monitoring and avoidance of excessively rapid correction)\*
- Duration of treatment limited to 30 days due to the risk of hepatotoxicity

\*Avoid fluid restriction during the first 24 hours; advise patients to continue to ingest fluids in response to thirst.

### Additional Inclusion Criteria

For women of childbearing potential:

- Per the manufacturer's prescribing information, tolvaptan (SAMSCA) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Based on animal data, tolvaptan may cause fetal harm. In addition, breastfeeding is not recommended.

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