



Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	November 16, 2012 November 23, 2015, July 7, 2017

SAMSCA[®] (tolvaptan)

LENGTH OF AUTHORIZATION: Date of service or per prescription (up to 30 days)

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Must have a diagnosis hyponatremia:
 - serum sodium level may be below 125 mEq/L **-OR-**
 - serum sodium level ≥ 125 but patient is symptomatic and has resisted correction with fluid restriction

DOSING AND ADMINISTRATION:

- Did the patient receive initial dose or re-initiation of therapy in the hospital? YES NO
If yes, supporting documentation required.
- Patients should be in a hospital for initiation and re-initiation of therapy to evaluate the therapeutic response and because too rapid correction of hyponatremia can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death.
- The usual starting dose for Samsca is 15 mg administered once daily without regard to meals. Increase the dose to 30 mg once daily, after at least 24 hours, to a maximum of 60 mg once daily, as needed to achieve the desired level of serum sodium.
- Dosage form: 15mg and 30mg tablets