

## SPECIALTY GUIDELINE MANAGEMENT

### SAMSCA (tolvaptan) tolvaptan (generic)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

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/tolvaptan. It has not been established that raising serum sodium with Samsca/tolvaptan provides a symptomatic benefit to patients.

All other indications are considered experimental/investigational and are not medically necessary.

##### II. CRITERIA FOR INITIAL APPROVAL

##### **Hypervolemic/Euvolemic Hyponatremia**

Authorization of 30 days may be granted for members prescribed the requested drug when all of the following criteria are met:

- A. Therapy was initiated (or re-initiated) in the hospital, for hypervolemic or euvolemic hyponatremia; and
- B. Serum sodium was less than 125 mEq/L or serum sodium was less than 135 mEq/L with symptoms (e.g., nausea, vomiting, headache, lethargy, confusion) at the time of therapy initiation; and
- C. The member will not receive the requested drug continually for greater than 30 days.

##### III. REFERENCES

1. Samsca [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; June 2018.
2. Tolvaptan [package insert]. Weston, FL: Apotex Corp; June 2019.
3. Micromedex Solutions [electronic version]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com/>. Accessed December 11, 2019.
4. Clinical Pharmacology [database online]. Atlanta, GA: Elsevier, Inc.; 2019. <https://www.clinicalkey.com/pharmacology/> Accessed December 11, 2019.
5. Lexicomp Online®, AHFS® Drug Information, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; <http://online.lexi.com> Accessed December 11, 2019.