Reference number
2181-A

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.
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.
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.; April 2021.
2. Tolvaptan [package insert]. Parsippany, NJ: Ascend Laboratories, LLC; May 2022.
3. Hoorn EJ, Zietse R. Diagnosis and treatment of hyponatremia: Compilation of the guidelines. *J Am Soc Nephol.* 2017; 28(5):1340-1349.