

# Specialty Guideline Management

## tolvaptan-Samsca

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Samsca	tolvaptan

### 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 Indications<sup>1,2</sup>

Samsca/tolvaptan is indicated for 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).

#### Limitations of Use

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.

# Coverage Criteria

## Hypervolemic or Euvolemic Hyponatremia<sup>1-3</sup>

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

- Therapy was initiated (or re-initiated) in the hospital for hypervolemic or euvolemic hyponatremia.
- 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.
- The member will not receive the requested drug continually for greater than 30 days.

## References

1. Samsca [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; April 2021.
2. Tolvaptan [package insert]. Piscataway, NJ: Novadoz Pharmaceuticals LLC; May 2023.
3. Hoorn EJ, Zietse R. Diagnosis and treatment of hyponatremia: Compilation of the guidelines. J Am Soc Nephrol. 2017; 28(5):1340-1349.