CVS Caremark®

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| Reference number(s) |
| 2181-A |

# 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 |
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| 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 Indications1

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.

## Coverage Criteria

### Hypervolemic/Euvolemic Hyponatremia:1-3

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]. Parsippany, NJ: Novadoz Pharmaceuticals LLC; March 2023.
3. Hoorn EJ, Zietse R. Diagnosis and treatment of hyponatremia: Compilation of the guidelines. J Am Soc Nephol. 2017; 28(5):1340-1349.