

**Generic Name:** Tolvaptan**Preferred:** N/A**Therapeutic Class or Brand Name:** Samsca**Non-preferred:** N/A**Applicable Drugs (if Therapeutic Class):** N/A**Date of Origin:** 12/1/2016**GPI Code:** 3045406000**Date Last Reviewed / Revised:** 1/20/2020

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

- I. Documented diagnosis of clinically significant hypervolemic or euvolemic hyponatremia.
- II. Documentation that patient had of one of the following A or B prior to starting Samsca:
  - A. Serum sodium less than 125 mEq/L.
  - B. Serum sodium greater or equal to 125 mEq/L, and patient has hyponatremia that is symptomatic and has resisted correction with fluid restriction.
- III. Documentation that Samsca was initiated or re-initiated in the hospital.
- IV. Minimum age requirement: 18 years old.

## EXCLUSION CRITERIA

- Patients with autosomal dominant polycystic kidney disease (ADPKD) outside of FDA-approved REMS.
- Need to raise serum sodium acutely.
- Patients who are unable to respond appropriately to thirst.
- Hypovolemic hyponatremia.
- Concomitant use of strong CYP 3A inhibitors such as clarithromycin, ketoconazole, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir, nefazodone, and telithromycin.
- Anuria.
- Patients with underlying liver disease, including cirrhosis.

## OTHER CRITERIA

- Treatment duration should be limited to 30 days to minimize the risk of liver injury.

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- Doses are limited to 60 mg per day. The quantity is limited to a maximum of what is needed to complete 30 days.

## APPROVAL LENGTH

- **Authorization:** Up to a total of 30 days.
- **Re-Authorization:** N/A

## APPENDIX

N/A

## REFERENCES

1. Samsca® [Package Insert]. Rockville, MD: Otsuka Pharmaceutical. June 2018. Available at: <https://www.otsuka-us.com/media/static/Samsca-PI.pdf>.
2. Medi-Span®.
3. Braun NM, et. al., Diagnosis and management of sodium disorders: hyponatremia and hypernatremia. Am Fam Physician. 2015 Mar 1;91(5):299-307. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/25822386>.

## HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
1/20/2020	1. <b>Removed</b> "http://www.bcbsnc.com/assets/services/public/pdfs/formulary/Samsca_Criteria.pdf" Added "https://www.ncbi.nlm.nih.gov/pubmed/25822386" <b>under References</b> .
12/18/2018	1. <b>Added</b> "Patients with autosomal dominant polycystic kidney disease (ADPKD) outside of FDA-approved REMS" <b>under Exclusion Criteria</b> .
1/16/2018	1. <b>Updated</b> "https://www.samsca.com/Content/themes/base/documents/prescribing-information-samsca.pdf" <b>to</b> "https://www.otsuka-us.com/media/static/Samsca-PI.pdf" <b>under References</b> . 2. <b>Removed</b> "https://d1tpfj3hind0fx.cloudfront.net/Media/Documents/UMC/0090Samsca.pdf" <b>from References</b> (link no longer valid).

**DISCLAIMER:** Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.