# tolvaptan (Samsca®)

EOCCO POLICY

## Policy Type: PA/SP  Pharmacy Coverage Policy: EOCCO099

### Description

Tolvaptan (Samsca) is an orally administered vasopressin V2-receptor antagonist which causes an increase in urine water excretion that results in an increase in free water clearance (aquaresis), a decrease in urine osmolality, and a resulting increase in serum sodium concentrations.

### Length of Authorization

- Initial: one month
- Renewal: no renewal

### Quantity limits

| Product Name | Dosage Form | Indication | Quantity Limit | DDID |
|---|---|---|---|---|
| tolvaptan (Samsca) | 15 mg tablet | Hypervolemic or euvolemic hyponatremia | 30 tablets/365 days | 143433 |
| | 30 mg tablet | | 60 tablets/365 days | 143434 |

### Initial Evaluation

I. Tolvaptan (Samsca) may be considered medically necessary when the following criteria below are met:
   A. Member is 18 years of age or older; **AND**
   B. Medication is prescribed by, or in consultation with an endocrinologist or nephrologist; **AND**
   C. Medication was initiated in the hospital; **AND**
   D. The requested treatment course will not exceed a 30-day duration per FDA recommendation; **AND**
   E. A diagnosis of **clinically significant hypervolemic or euvolemic hyponatremia** when the following are met:
      1. Serum sodium is less than 125 mEq/L; **OR**
      2. Serum sodium is greater than 125 mEq/L **and** patient has symptomatic hyponatremia (e.g., nausea, vomiting, headache, lethargy, confusion) that has resisted correction with fluid restriction

II. Tolvaptan (Samsca) is considered investigational when used for all other conditions, including but not limited to:
   A. Autosomal Dominant Polycystic Kidney Disease (ADPKD)

B. Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms

## Supporting Evidence

I. Per the label, tolvaptan (Samsca) is indicated for the 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).
II. Safety and effectiveness of tolvaptan (Samsca) in pediatric patients has not been established.
III. Per the label, patients should be in a hospital for initiation and re-initiation of therapy to evaluate the therapeutic response and because too rapid correction of hyponatremia can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death.
IV. To minimize the risk of liver injury, tolvaptan (Samsca) should not be administered for more than 30 days. Based largely on the hepatic injury noted in the TEMPO trial, on April 2013 the FDA recommended that: “treatment should be stopped if the patient develops signs of liver disease. Treatment duration should be limited to 30 days or less, and use should be avoided in patients with underlying liver disease, including cirrhosis”.
V. It has not been established that raising serum sodium with tolvaptan (Samsca) provides a symptomatic benefit to patients.

## Investigational or Not Medically Necessary Uses

I. Autosomal Dominant Polycystic Kidney Disease (ADPKD)
    A. Jynarque (tolvaptan) is another tolvaptan product that is indicated to slow kidney function decline in adults at risk of rapidly-progressing ADPKD; however, the recommended dosing in Jynarque differs from the Samsca product. Per the tolvaptan (Samsca) label, because of the risk of hepatotoxicity, tolvaptan should not be used for ADPKD outside of the FDA-approved REMS.
II. Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms.
    A. Tolvaptan (Samsca) has not been studied in a setting of urgent need to raise serum sodium acutely.

## References

1. Samsca [prescribing information]. Rockville, MD: Otsuka Pharmaceuticals; April 2018.
2. Torres VE, Chapman AB, Devuyst O, et al. Tolvaptan in patients with autosomal dominant polycystic kidney disease. N Engl J Med. 2012;367(25):2407-18.
3. Diagnosis, evaluation, and treatment of hyponatremia: expert panel recommendations. Verbalis JG, Goldsmith SR, Greenberg A,Korzelius C, Schrier RW, Sterns RH, Thompson CJ. https://doi.org/10.1016/j.amjmed.2013.07.006Am J Med. 2013;126:0.3. Spasovski G, Vanholder R, Allolio B, et al. Clinical practice guideline on diagnosis and treatment of hyponatraemia. Neprhol DialTransplant 2014; 29 Suppl 2:i1.

## Policy Implementation/Update:

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| Date Created | November 2019 |
| Date Effective | November 2019 |
| Last Updated | |
| Last Reviewed | |

| Action and Summary of Changes | Date |
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