

Generic Name: Tolvaptan

Therapeutic Class or Brand Name: Samsca,
Jynarque

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 11/16/2022

Date Last Reviewed / Revised: 11/16/2022

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I or II are met)

- I. Documented diagnosis of clinically significant hypervolemic or euvolemic hyponatremia and all the criteria A through E are met:
 - A. Documentation that the patient had of one of the following 1 or 2 prior to starting tolvaptan:
 1. Serum sodium less than 125 mEq/L.
 2. Serum sodium greater or equal to 125 mEq/L, and the patient has symptomatic hyponatremia and has resisted correction with fluid restriction.
 - B. Documentation that tolvaptan was initiated or re-initiated in the hospital.
 - C. The request is for Samsca and will not exceed 30 days
 - D. Minimum age requirement: 18 years old.
 - E. Patient has a documented clinically significant treatment failure, adverse event, or contraindication with generic tolvaptan.
- II. Rapidly Progressing Autosomal Dominant Polycystic Kidney Disease (ADPKD) and all the criteria A through E are met:
 - A. The medication is used to slow kidney function decline in adults at risk of rapidly progressing ADPKD.
 - B. Test results for the patient's liver function laboratory values (ALT, AST, and bilirubin), and it will continue to be monitored during therapy.
 - C. The patient does not have stage 5 chronic kidney disease (defined as glomerular filtration rate < 15 mL/min/1.73 m² or receiving dialysis).
 - D. Treatment must be prescribed by or in consultation with a nephrologist.
 - E. 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 for Samsca for hypervolemic or euvolemic hyponatremia should be limited to 30 days to minimize the risk of liver injury.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Samsca: 60mg once daily up to a total of 30 days. The quantity is limited to a maximum of what is needed to complete 30 days.
- Jynarque: 60 mg/day in divided doses.

APPROVAL LENGTH

- **Authorization:**
 - Samsca for hypervolemic or euvolemic hyponatremia: Up to a total of 30 days.
 - Jynarque and request is for autosomal Dominant Polycystic Kidney Disease (ADPKD): 6 months
- **Re-Authorization:**
 - Hypervolemic or euvolemic hyponatremia: NA
 - The Request is for autosomal Dominant Polycystic Kidney Disease (ADPKD): 1 year. An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective (for example, kidney function decline has slowed, and kidney pain has improved since the start of Jynarque).

APPENDIX

N/A

REFERENCES

1. Samsca®. Prescribing information. Otsuka Pharmaceutical. 2021. Accessed November 16, 2022. <https://www.otsuka-us.com/media/static/Samsca-PI.pdf>.

2. Jynarque. Prescribing information. Otsuka America Pharmaceutical, Inc.; 2020. Accessed November 16, 2022. <https://www.otsuka-us.com/sites/g/files/qhldwo6181/files/media/static/JYNARQUE-PI.pdf>.
3. Braun MM, Barstow CH, Pyzocha NJ. Diagnosis and management of sodium disorders: hyponatremia and hypernatremia. *Am Fam Physician*. 2015;91(5):299-307. Accessed November 16, 2022. <https://www.ncbi.nlm.nih.gov/pubmed/25822386>.
4. Cornec-Le Gall E, Alam A, Perrone RD. Autosomal dominant polycystic kidney disease. *Lancet*. 2019;393(10174):919-935. Accessed November 16, 2022. doi:10.1016/S0140-6736(18)32782-X
5. Torres VE. Pro: Tolvaptan delays the progression of autosomal dominant polycystic kidney disease. *Nephrol Dial Transplant*. 2019;34(1):30-34. Accessed November 16, 2022. doi:10.1093/ndt/gfy297

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.