Generic Name: Tolvaptan

Therapeutic Class or Brand Name: N/A

Applicable Drugs (if Therapeutic Class): Jynarque, Tolvaptan (Jynarque generic), Tolvaptan Therapy Pack (generic Jynarque), Samsca, Tolvaptan (Samsca generic)

Preferred: Tolvaptan (Jynarque generic) Tolvaptan Therapy Pack (Jynarque generic), Tolvaptan (Samsca generic)

Non-preferred: Jynarque, Samsca

Date of Origin: 11/16/2022

Date Last Reviewed / Revised: 4/29/2025

PRIOR AUTHORIZATION CRITERIA

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

I. Documented diagnosis of one of the following conditions A or B AND must meet ALL criteria under applicable diagnosis.

A. Clinically significant chronic hypervolemic or euvolemic hyponatremia

1. Documentation that the patient had one of the following a or b prior to starting tolvaptan:
    a. Serum sodium less than 125 mEq/L.
    b. Serum sodium greater or equal to 125 mEq/L, and the member has symptomatic hyponatremia and has resisted correction with fluid restriction.
2. Documentation that tolvaptan was initiated or re-initiated in the hospital.
3. If the request is for Samsca, there must be documented treatment failure or contraindication to generic tolvaptan.

B. Rapidly Progressing Autosomal Dominant Polycystic Kidney Disease (ADPKD)

1. The request is for Tolvaptan (Jynarque generic) or Jynarque and is prescribed by a provider certified in the Tolvaptan for ADPKD Shared System REMS program.
2. Documentation that the member has a high risk for progression to end-stage renal disease (ESRD).
3. Documentation that liver function laboratory values (ALT, AST, and bilirubin) are appropriate before initiation and will continue to be monitored during therapy as required by the Tolvaptan for ADPKD Shared System REMS Program.
4. The patient does not have stage 5 chronic kidney disease (defined as glomerular filtrate rate < 15 mL/min/1.73 m2 or receiving dialysis).
5. If the request is for Jynarque, there must be a documented treatment failure or contraindication to tolvaptan (generic Jynarque) or tolvaptan therapy pack (generic Jynarque).

II. Minimum age requirement is 18 years.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented treatment failure or contraindication to the preferred product(s).

Exclusion Criteria

- Taking strong CYP3A inhibitors such as clarithromycin, ketoconazole, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir, nefazodone, and telithromycin.
- Unable to sense or respond to thirst.
- Anuria.
- Samsca, generic tolvaptan (additional contraindications):
    - Hypovolemic hyponatremia.
    - Hypernatremia.
    - Need to raise serum sodium acutely.
    - Use in patients with ADPKD outside of the FDA-approved REMS.
- Jynarque, generic tolvaptan (additional contraindications):
    - Patients with significant liver impairment or injury (not applicable to uncomplicated polycystic liver disease).
    - Uncorrected abnormal blood sodium concentrations.
    - Uncorrected urinary outflow obstruction.
    - Hypovolemia.

Other Criteria

- Treatment duration for tolvaptan (Samsca generic) or Samsca for hypervolemic or euvolemic hyponatremia should be limited to 30 days to minimize the risk of liver injury.
- Tolvaptan (Samsca generic) and Tolvaptan (Jynarque generic) are not interchangeable.

Quantity / Days Supply Restrictions

- Tolvaptan (generic Samsca), 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.
- Tolvaptan (Jynarque generic), tolvaptan therapy pack (Jynarque generic), Jynarque: 120mg/day in divided doses.

Approval Length

- **Authorization:**
    - Tolvaptan (Samsca generic) or Samsca for hypervolemic or euvolemic hyponatremia: Up to a total of 30 days.
    - Tolvaptan (Jynarque generic), tolvaptan therapy pack (Jynarque generic) or Jynarque 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 April 29, 2025. https://www.otsuka-us.com/media/static/Samsca-PI.pdf.
2. Jynarque. Prescribing information. Otsuka America Pharmaceutical, Inc.; 2020. Accessed April 29, 2025. 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 April 29, 2025. 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 April 29, 2025. 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 April 29, 2025. doi:10.1093/ndt/gfy297
6. Chapman, AB, Devuyst, O, Eckardt, KU, et al. Autosomal-dominant polycystic kidney disease (ADPKD): executive summary from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. *Kidney Int* 2015;88:17-27. Accessed April 29, 2025. Doi: 10.1038/ki.205.59

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.