Generic Name: Tolvaptan

Therapeutic Class or Brand Name: N/A

Applicable Drugs (if Therapeutic Class): Jynarque, Samsca, tolvaptan/tolvaptan therapy pack (generic Jynarque), tolvaptan (generic Samsca)

Preferred: tolvaptan/tolvaptan therapy pack (generic Jynarque), tolvaptan (generic Samsca)

Non-preferred: Jynarque, Samsca

Date of Origin: 11/16/2022

Date Last Reviewed / Revised: 7/9/2026

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 < 125 mEq/L.

b. Serum sodium ≥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 brand Samsca, there must be documented treatment failure or contraindication to generic Samsca.

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

1. Documentation that the member has a high risk for progression to end-stage renal disease (ESRD) defined as a or b:

a. Mayo class 1C to 1E.

b. Historical rate of eGFR decline (≥3 ml/min per 1.73 m^2 per year) after alternate etiologies (such as vascular disease, uncontrolled hypertension, diabetic nephropathy, proteinuria ≥1 g/d) and/or acute kidney injury) for eGFR decline have been excluded.

2. Documentation of eGFR ≥25 ml/min per 1.73 m^2.

3. If the request is for brand Jynarque, there must be a documented treatment failure or contraindication to generic Jynarque.

II. Minimum age: 18 years old.

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

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Tolvaptan (generic or brand Samsca): Quantity necessary to supply dose titration up to a maximum dose of 60mg once daily for up to a total of a 30 days supply
- Tolvaptan and tolvaptan therapy pack (generic or brand Jynarque): Quantity necessary to supply dose up to 120mg/day (in divided doses) for a 30 days supply.

APPROVAL LENGTH

- **Authorization:**

- Hypervolemic or euvolemic hyponatremia:
  - Tolvaptan (generic or brand Samsca): 30 days maximum
- ADPKD
  - Tolvaptan or tolvaptan therapy pack (generic or brand Jynarque): 6 months

- **Re-Authorization:**
  - Hypervolemic or euvolemic hyponatremia: N/A
  - 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 America Pharmaceutical, I. 2021. Accessed July 9, 2026. https://www.otsuka-us.com/media/static/Samsca-PI.pdf.
2. Jynarque. Prescribing information. Otsuka America Pharmaceutical, Inc.; 2025. Accessed July 9, 2026. https://www.otsuka-us.com/sites/g/files/qhldwo6181/files/media/static/JYNARQUE-PI.pdf.
3. Miller NE, Rushlow D, Stacey SK. Diagnosis and management of sodium disorders: hyponatremia and hypernatremia. *Am Fam Physician*. 2023;108(5):476-486.
4. Kidney Disease: Improving Global Outcomes (KDIGO) ADPKD Work Group. KDIGO 2025 Clinical Practice Guideline for the Evaluation, Management, and Treatment of Autosomal Dominant Polycystic Kidney Disease (ADPKD). *Kidney Int.* 2025;107(2S):S1-S239. doi: 10.1016/j.kint.2024.07.009

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.