Effective date: 4/1/2020
Reviewed: 1/2020, 3/2021, 3/2022, 3/2023, 3/2024, 3/2025, 6/2026 Scope: Medicaid

Tolvaptan (generic Jynarque)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Tolvaptan is indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 6 months may be granted for treatment of autosomal dominant polycystic kidney disease (ADPKD) when all of the following criteria are met:

A. Documentation that the member is 18 years of age or older and with a diagnosis of ADPKD as confirmed by any of the following:
    1. In members aged 18 to less than 40 years with a first degree relative with ADPKD: greater than or equal to 3 cysts (unilateral or bilateral) using any radiologic method
    2. In members aged 40 to less than 60 years with a first degree relative with ADPKD: greater than or equal to 2 cysts per kidney using any radiologic method
    3. In members aged 60 or older with a first degree relative with ADPKD: greater than or equal to 4 cysts per kidney using any radiologic method
    4. In members with no family history (no first degree relative with disease): positive genetic test for ADPKD (mutation in PKD1 or PKD2 gene)
B. Prescribed by or in consultation with a nephrologist or physician specializing in the management of ADPKD.
C. The member's estimated glomerular filtration rate (eGFR) is greater than or equal to 25 mL/min/1.73m^2 and documentation of one of the following:
    1. The member has or is at risk for rapidly progressing disease as confirmed by height-adjusted total kidney volume compatible with Mayo class 1C, 1D, or 1E disease.
    2. The member has a historical rate of eGFR decline of ≥3 mL/min/1.73m^2
D. The member does not have any of the following contraindications: liver impairment or injury, member is concurrently taking a strong CYP3A4 inhibitor, member does not have the ability to sense or respond to thirst, uncorrected abnormal serum sodium concentrations (particularly hypernatremia), hypovolemia, anuria, or uncorrected urinary outflow obstruction.

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when the member has demonstrated a beneficial response to tolvaptan therapy (e.g., slowed kidney function decline, decreased kidney pain) and the member's estimated glomerular filtration rate (eGFR) is greater than or equal to 25 mL/min/1.73m^2.

IV. QUANTITY LIMIT

Tolvaptan pak 15-15mg, 30-15mg, 45-15mg, 60-30mg, 90-30mg has a quantity limit of 2 tablets per day. Tolvaptan 15mg & 30mg has a quantity limit of 1 tablet per day

V. REFERENCES

1. Jynarque [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; March 2025.
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3. Torres VE, Devuyst O, Chapman AB, et al; for the REPRISE Trial Investigators. Rationale and design of a clinical trial investigating tolvaptan safety and efficacy in autosomal dominant polycystic kidney disease. *Am J Nephrol.* 2017;45(3):257-266.
4. 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(1):17-27.
5. Srivastava A, Patel N. Autosomal dominant polycystic kidney disease. *Am Fam Physician.* 2014 Sep 1;90(5):303-307.
6. Gansevoort RT, Arici M, Benzing T, et al. Recommendations for the use of tolvaptan in autosomal dominant polycystic kidney disease: a position statement on behalf of the ERA-EDTA Working Groups on Inherited Kidney Disorders and European Renal Best Practice. *Nephrol Dial Transplant.* 2016;31(3):337-348.
7. Pei Y, Obaji J, Dupuis A, et. Al. Unified criteria for ultrasonographic diagnosis of ADPKD. *J Am Soc Nephrol.* 2009;20:205-212.
8. KDIGO 2025 Clinical Practice Guideline for the Evaluation, Management, and Treatment of Autosomal Dominant Polycystic Kidney Disease (ADPKD). Devuyst, Olivier et al. Kidney International, Volume 107, Issue 2, S1 - S239.