

ALASKA MEDICAID  
Prior Authorization Criteria

**Jynarque™  
(tolvaptan)**

**EDA INDICATIONS AND USAGE**<sup>1</sup>

Jynarque™ (tolvaptan) is a selective vasopressin V2-receptor antagonist indicated to slow kidney function decline on adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

**APPROVAL CRITERIA**<sup>1,2</sup>

1. Patient is 18 years of age or older **AND**;
2. Patient has a diagnosis of autosomal dominant polycystic kidney disease and is at risk for kidney function decline **AND**;
3. Is being prescribed by or in consultation with a nephrologist **AND**;
4. The patient has had a liver function test, showing results deemed appropriate prior to treatment **AND**;
5. Prescriber agrees to check liver function at week 2, 4 and then monthly during the first 18 months of therapy.

**DENIAL CRITERIA**<sup>1,2</sup>

1. Failure to meet approval criteria **OR**;
2. Patient has history of significant liver impairment or injury **OR**;
3. Patient has uncorrected abnormal blood sodium level **OR**;
4. Patient is unable to sense or appropriately respond to thirst **OR**;
5. Patient is hypovolemic, anuric, or has an uncorrected urinary outflow obstruction **OR**;
6. Patient is concomitantly using a strong CYP 3A inhibitor.

**CAUTIONS**<sup>1</sup>

- Serious liver injury has occurred in patients taking Jynarque™.
- Monitor for hypernatremia, dehydration, and hypovolemia.
- Dose reductions of Jynarque™ may be recommended for patients taking a moderate CYP 3A inducer.

**DURATION OF APPROVAL**

- Initial Approval: up to 90 days
- Reauthorization Approval: up to 12 months

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**QUANTITY LIMIT**

- 45mg and 15mg kit - 56 tablets per 28 days
- 60mg and 30mg kit - 56 tablets per 28 days
- 90mg and 30mg kit - 56 tablets per 28 days
- 15 mg tablets – 30 per 30 days
- 30mg tablets – 30 per 30 days

**REFERENCES / FOOTNOTES:**

1. Jynarque™ [prescribing information]. Rockville, M: Otsuka America Pharmaceutical Inc.; February 2019.
2. Torres VE, Chapman AB, Devuyst O, et al. for the Tempo 3:4 trial investigators. Tolvaptan in patients with autosomal dominant polycystic kidney disease. New England Journal of Medicine, 2012;367(25):2407-2418.