

<b>Policy Name:</b>	<b>Jynarque (tolvaptan)</b>	<b>Policy #:</b>	<b>2649P</b>
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### Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Jynarque.

### Statement of the Policy

Health Alliance Medical Plans will approve the use of Jynarque under the specialty pharmacy benefit when the following criteria have been met.

### Criteria

#### 1. Coverage Criteria

- 1.1 Diagnosis of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)
- 1.2 Prescribed by a nephrologist (kidney doctor)

#### 2. Exclusion Criteria

- 2.1 Hypovolemia (low fluid level)
- 2.2 Uncorrected Hyponatremia (high sodium level)
- 2.3 Use in patients unable to sense or appropriately respond to thirst
- 2.4 Clinically relevant hepatic impairment (liver problems)
- 2.5 Anuria (lack of urination)
- 2.6 Pregnancy
- 2.7 Breastfeeding

#### 3. Approval Period

- 3.1 Initial: 12 months
- 3.2 Reauthorization: 12 months with documented clinical benefit from therapy

### CPT Codes

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### HCPCS Codes

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### References

1. Jynarque (tolvaptan) [prescribing information]. Rockville, MD: Otsuka America Pharmaceuticals Inc; October 2020.
2. Chebib FT, Perrone RD, Chapman AB, et al. A Practical Guide for Treatment of Rapidly Progressive ADPKD with Tolvaptan. *J Am Soc Nephrol* 2018; 29:2458.
3. Devuyst O, Chapman AB, Gansevoort RT, et al. Urine osmolality, response to tolvaptan, and outcome in autosomal dominant polycystic kidney disease: results from the TEMPO 3:4 trial. *J Am Soc Nephrol*. 2017;28(5):1592-1602.

4. Torres VE. Pro: Tolvaptan delays the progression of autosomal dominant polycystic kidney disease. Nephrol Dial Transplant 2019; 34:30.

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#### DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.

