

Drug Therapy Guidelines

Jynarque™ (tolvaptan)

Applicable

Medical Benefit		Effective: 8/15/18
Pharmacy- Formulary 1	x	Next Review: 12/18
Pharmacy- Formulary 2	x	Date of Origin: 6/18
Pharmacy- Formulary 3/Exclusive	x	Review Dates: 6/18
Pharmacy- Formulary 4/AON	x	

I. Medication Description

Jynarque is a selective vasopressin V2-receptor antagonist with an affinity for the V2-receptor that is 1.8 times that of native arginine vasopressin (AVP). Decreased binding of vasopressin to the V2-receptor in the kidney lowers adenylate cyclase activity resulting in a decrease in intracellular adenosine 3', 5'-cyclic monophosphate (cAMP) concentrations. Decreased cAMP concentrations prevent aquaporin 2 containing vesicles from fusing with the plasma membrane, which in turn causes an increase in urine water excretion, an increase in free water clearance (aquaresis) and a decrease in urine osmolality.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage is provided when the following criteria are met:

- The member is at least 18 years of age **AND**
- The medication is prescribed by a nephrologist **AND**
- The member has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) as confirmed by imaging (ultrasound, CT, or MRI) OR genetic testing **AND**
- The member is at high risk of developing OR has rapidly progressing ADPKD

IV. Quantity Limitations

Coverage is available for 56 tablets per 28 days

V. Coverage Duration

Coverage is available for 6 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Continued positive clinical response (i.e. slowing of the rate of decline in renal function) **AND**

- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Available as 7-day (14 tablets) or 28-day (56 tablets) blister cards containing:

- Jynarque 45mg / Jynarque 15mg
- Jynarque 60mg / Jynarque 30mg
- Jynarque 90mg / Jynarque 30mg

VIII. Summary of Policy Changes

- 8/15/18: new policy

IX. References

1. Jynarque™ [prescribing information]. Tokyo, Japan: Otsuka Pharmaceutical Co., Ltd.; April 2018.
2. Jynarque. Clinical Pharmacology, accessed online 5/2018. www.clinicalpharmacology.com. Elsevier/Gold Standard.
3. Torres V, Bennett W. Diagnosis of and screening for autosomal dominant polycystic kidney disease. UpToDate. Waltham, Massachusetts: www-uptodate-com. Accessed May 21, 2018.
4. Chapman A, Rahbari-Oskoui F, Bennett W. Course and treatment of autosomal dominant polycystic kidney disease. UpToDate. Waltham, Massachusetts: www-uptodate-com. Accessed May 21, 2018.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.