Pharmacy Policy Bulletin: J-0778 Jynarque (tolvaptan) – Commercial and Healthcare Reform	
Number: J-0778	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0778-011	**Original Date:** 08/01/2018
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Jynarque (tolvaptan)
FDA-Approved Indication(s):	• Slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

Background:	• Jynarque is a selective vasopressin V2-receptorantagonist. Jynarque blocks vasopressin, an antidiuretic hormone secreted by the pituitary gland, which plays a key role in the fluid balance of the kidneys. By blocking vasopressin, Jynarque can decrease cyst-cell proliferation and chloride-dependent fluid secretion into cysts, which ultimately can reduce cyst growth.
	• In ADPKD, fluid-filled cysts develop and enlarge in both kidneys, eventually leading to kidney failure.
	• The KDIGO 2025 clinical practice guideline for the evaluation, management, and treatment of ADPKD defines rapid disease progression as either of the following:
	  ○ Estimated glomerular filtration rate (eGFR) decline ≥ 3 mL/min/1.73 m^2 per year.
	  ○ Mayo ADPKD classification class of 1C to 1E. The Mayo classification for prediction of disease progression in ADPKD uses height adjusted total kidney volume (htTKV) and age. In general, class 1C, 1D and 1E patients will have rapid disease progression and qualify for treatment.
	• Risks and benefits of Jynarque have not been studied in patients with stage 5 chronic kidney disease (CKD) or dialysis.
	• Stage 5 CKD is an eGFR less than 15 mL/min/1.73m^2 and the kidneys are very close to failure or have completely failed.
	• ICD-10 Code Information:
	  ○ Q61.2 “Polycystic kidney, adult type” and Q61.3 “Polycystic Kidney, unspecified” may apply to Jynarque; however, the prescriber must specify the disease is classified as autosomal dominant.
	• Prescribing Considerations:

	○ Jynarque has a black box warning and REMS program for risk of serious liver injury including acute liver failure requiring liver transplantation. The program ensures patients are monitored at baseline and periodically and are counseled on the risks of the medication. Measure alanine transaminase (ALT), aspartate aminotransferase (AST), and bilirubin before initiating treatment, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months and every 3 months thereafter. ○ Jynarque may cause hypernatremia, dehydration, and hypovolemia requiring intervention. ○ Samsca (tolvaptan) is not indicated for use in ADPKD. Jynarque and Samsca should not be used interchangeably or concurrently with each other.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Jynarque may be approved when all of the following criteria are met **(A. through D.)**:

A. The member is 18 years of age or older.

B. Jynarque is prescribed by or in consultation with a nephrologist.

C. The member has a diagnosis of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD) (no ICD-10 code) supported by one (1) of the following **(1. or 2.)**:

1. Historical decline in eGFR ≥ 3 mL/min/1.73 m^2 per year.

2. Mayo imaging classification of 1C, 1D, or 1E.

D. The member meets all of the following criteria **(1. and 2.)**:

1. The member does not have stage 5 chronic kidney disease.

2. The member is not receiving dialysis.

II. Reauthorization

When a benefit, reauthorization of Jynarque may be approved when all of the following criteria are met **(A. and B.)**:

A. The prescriber attests that decline in the member's kidney function (e.g., TKV, eGFR) has slowed.

B. The member meets all of the following criteria **(1. and 2.)**:

1. The member does not have stage 5 chronic kidney disease.

2. The member is not receiving dialysis.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Jynarque [package insert]. Rockville, MD: Otsuka Pharmaceutical Co., Ltd.; October 2020.
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3. Edwards ME, Chebib FT, Irazabal MV, et al. Long-Term Administration of Tolvaptan in Autosomal Dominant Polycystic Kidney Disease. *Clin J Am Soc Nephrol*. 2018;13(8):1153-1161.
4. Cornec Le Gall E. The PROPKD score: a new algorithm to predict renal survival in autosomal dominant polycystic kidney disease. *J Am Soc Nephrol*. 2016. Mar;27(3):942-51.
5. Grantham JJ, Chapman AB, Torres VE. Volume progression in autosomal dominant polycystic kidney disease: the major factor determining clinical outcomes. *Clin J Am Soc Nephrol*. 2006;1(1):148-157.
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7. Yu ASL, Shen C, Landsittel DP, et al; for the Consortium for Radiologic Imaging Studies of Polycystic Kidney Disease (CRISP). Baseline total kidney volume and the rate of kidney growth are associated with chronic kidney disease progression in autosomal dominant polycystic kidney disease. *Kidney Int*. 2018;93(3):691-699.
8. Irazabal MV, Rangel LJ, Bergstralh EJ, et al. Imaging classification of autosomal dominant polycystic kidney disease: a simple model for selecting patients for clinical trials. *J Am Soc Nephrol*. 2015;26(1):160-172.
9. Bhutani H, Smith V, Rahbari-Oskoui F, et al. A comparison of ultrasound and magnetic resonance imaging shows kidney length predicts chronic kidney disease in autosomal dominant polycystic kidney disease. *Kidney Int*. 2015;88(1):146–151.
10. Soroka S, Alam A, Bevilacqua M, et al. Assessing risk of disease progression and pharmacological management of autosomal dominant polycystic kidney disease: a Canadian expert consensus. *Can J Kidney Health Dis*. 2017;4.
11. Torres VE, Ahn C, Barten TRM, et al. KDIGO 2025 clinical practice guideline for the evaluation, management, and treatment of autosomal dominant polycystic kidney disease (ADPKD): executive summary. *Kidney Int.* 2025 Feb;107(2):234-254.