

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Jynarque (tolvaptan)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Jynarque (tolvaptan)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Jynarque (tolvaptan) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of autosomal dominant polycystic kidney disease and is at risk of or is experiencing rapidly progressing disease.

Jynarque (tolvaptan) may **not** be approved for the following:

- I. Individual has an uncorrected abnormal blood sodium level; **OR**
- II. Individual is unable to sense or appropriately respond to thirst; **OR**
- III. Individual has a diagnosis of hypovolemia; **OR**
- IV. Individual has an uncorrected urinary outflow obstruction; **OR**
- V. Individual is anuric; **OR**
- VI. Individual has underlying significant liver disease (not including uncomplicated polycystic liver disease); **OR**
- VII. Individual will be concurrently utilizing a strong CYP 3A inhibitor (such as, clarithromycin, ketoconazole, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir, nefazodone, and telithromycin) (FDA).

Notes: Jynarque (tolvaptan) has a black box warning for serious and potentially fatal liver injury. ALT, AST and bilirubin should be monitored before treatment initiation, at 2 weeks and 4 weeks after initiation, monthly for the first 18 months and every 3 months thereafter. Jynarque is available only through a restricted distribution program called the Jynarque REMS Program.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Chapman AB, Rahbari-Oskoui FF, Bennett WM. Course and treatment of autosomal dominant polycystic kidney disease. Updated April 30, 2018. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: June 28, 2018.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Jynarque (tolvaptan) tablets for oral use [product information]. Rockville, MD: Otsuka Pharmaceuticals Ltd.; April 2018. Available at: <https://www.otsuka-us.com/media/static/JYNARQUE-PI.pdf>. Accessed: June 27, 2018.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
6. US Food and Drug Administration. Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. Last updated November 14, 2017. Available at <https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractionslabeling/ucm093664.htm>. Accessed: June 27, 2018.

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