



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOLVAPTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOLVAPTAN	JYNARQUE	36348		GPI-10 (3045406000)	BRAND ≠ SAMSCA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - Therapy is prescribed by or given in consultation with a nephrologist
 - The patient has confirmed polycystic kidney status via CT or MRI imaging **AND** one of the following:
 - The patient has a genotype causative of ADPKD **OR**
 - The patient has a family history of confirmed polycystic kidney disease in one or both parents
 - The patient does not have End-Stage Renal Disease (ESRD; including no renal transplantation or dialysis)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

2. Is the patient at high risk of rapid progression of disease?

Examples of risk factors which may predicate higher risk progression include:

- *PKD1* genotype
- Hypertension
- Early onset of symptoms including proteinuria and hematuria
- Male gender
- Increased kidney size
- Increased left ventricular mass index
- Dipstick detectable proteinuria
- Low birth weight
- Decreased renal blood flow
- Increased urinary sodium excretion
- Increased low-density lipoprotein (LDL) cholesterol
- Increased plasma copeptin
- Higher serum uric acid levels
- High concentration of fibroblast growth factor (FGF)

If yes, **approve for 6 months for all strengths as follows:**

- **Jynarque 90mg-30mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 45mg-15mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 60mg-30mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 30-15mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 15-15mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 15mg (NDC 59148-0082-13) [FDB & Medi-Span]: #60 per 30 days.**
- **Jynarque 30 mg (NDC 59148-0083-13) [FDB & Medi-Span]: #30 per 30 days.**

APPROVAL TEXT: Renewal requires that the patient has not progressed to ESRD.

If no, do not approve.

INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for approval:

- A. You have autosomal dominant polycystic kidney disease (ADPKD: inherited disorder in which clusters of cysts develop in the kidneys)
- B. You are 18 years of age or older
- C. The requested medication is prescribed by or given in consultation with a nephrologist (kidney specialist)

(Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

- D. You have confirmed polycystic kidney status via CT or MRI imaging (type of lab imaging tests) **AND** one of the following:
1. You have a genotype that causes of autosomal dominant polycystic kidney disease (inherited disorder in which clusters of cysts develop in the kidneys) **OR**
 2. You have a family history of confirmed polycystic kidney disease in one or both parents
- E. You do not have End-Stage Renal Disease (ESRD: advanced kidney disease) including no renal transplantation (kidney transplant) or dialysis
- F. You are at high risk of rapidly progressing autosomal dominant polycystic kidney disease

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD) **AND** meet the following criterion?
- The patient has not progressed to End-Stage Renal Disease (ESRD)

If yes, **approve for 12 months for all strengths as follows:**

- **Jynarque 90mg-30mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 45mg-15mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 60mg-30mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 30-15mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 15-15mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 15mg (NDC 59148-0082-13) [FDB & Medi-Span]: #60 per 30 days.**
- **Jynarque 30 mg (NDC 59148-0083-13) [FDB & Medi-Span]: #30 per 30 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for renewal:

- A. You have autosomal dominant polycystic kidney disease (ADPKD: inherited disorder in which clusters of cysts develop in the kidneys)
- B. You have NOT progressed to end stage renal (kidney) disease (ESRD)

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RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jynarque.

REFERENCES

- Jynarque [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/29/20

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P&T Approval: 07/18