



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOLVAPTAN

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

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 in consultation with a nephrologist
 - The patient does not have end-stage renal disease (ESRD; including no renal transplantation or dialysis)

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

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

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. Therapy is prescribed by or in consultation with a nephrologist (kidney specialist)
- D. You do not have end-stage renal disease (ESRD: advanced kidney disease) including no renal transplantation (kidney transplant) or dialysis

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.

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TOLVAPTAN

GUIDELINES FOR USE (CONTINUED)

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:

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

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.

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TOLVAPTAN

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.; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/23

Created: 08/18

Client Approval: 02/23

P&T Approval: 01/23