PRIOR AUTHORIZATION POLICY

POLICY: Tolvaptan Products – Jynarque Prior Authorization Policy
- Jynarque® (tolvaptan tablets – Otsuka)

REVIEW DATE: 06/26/2024

OVERVIEW

Jynarque, a selective vasopressin V_2-receptor antagonist, is indicated to slow kidney function decline in adults at risk of rapidly-progressing **autosomal dominant polycystic kidney disease** (ADPKD).[1]

Disease Overview

ADPKD is a heterogeneous, inherited kidney disorder associated with the development of kidney cysts, which result in kidney pain, hypertension, renal failure, and other clinical sequelae.[2-5] The condition is a common cause of end-stage renal disease; however, other organs are also impacted (e.g., hepatic and vascular systems). Progressive kidney enlargement occurs; however, manifestations generally do not occur until later in life (fourth decade) due to compensatory renal mechanisms. If a parent has the condition, a child has a 50% chance of inheritance. Approximately 600,000 people in the US have this condition.

Guidelines

The European Renal Association Working Groups on Inherited Kidney Disorders, the European Rare Kidney Disease Reference Network, and the Polycystic Kidney Disease International published a consensus statement regarding use of tolvaptan in ADPKD (2022).[7] A confirmed annual estimated glomerular filtration rate decline ≥ 3.0 mL/min/1.73 m^2 over a period of ≥ 4 years defines rapid progression. Also, a Mayo Classification of 1D or 1E indicates rapid disease progression. Patients with Mayo Classification of 1C should be further evaluated for additional evidence of rapid disease progression. Total kidney volume changes should not be used as a marker of progression in individual patients. Finally, Jynarque should be discontinued when the patient approaches kidney failure (i.e., the need for renal replacement therapy).

The National Kidney Foundation and the Polycystic Kidney Disease Foundation list tolvaptan as an FDA-approved treatment option for patients with ADPKD.[5,8]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Jynarque. All approvals are provided for the duration noted below. Due to the specialized skills required for evaluation and diagnosis of patients treated with Jynarque as well as the monitoring required for adverse events and long-term efficacy, approval requires Jynarque to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Jynarque is recommended in those who meet the following:

FDA-Approved Indication

1. **Autosomal Dominant Polycystic Kidney Disease.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** According to the prescriber, the patient has rapidly-progressing autosomal dominant polycystic kidney disease; AND
     Note: Examples of rapidly declining renal function include estimated glomerular filtration rate decline of ≥ 3.0 mL/min/1.73 m^2, and Mayo Classification of 1D or 1E.
   - **C)** Patient does not have Stage 5 chronic kidney disease; AND
     Note: Stage 5 chronic kidney disease is defined as glomerular filtration rate < 15 mL/min/1.73 m^2 or receiving dialysis.
   - **D)** The medication is prescribed by or in consultation with a nephrologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Jynarque is not recommended in the following situations:

1. **Patient is Currently Receiving Samsca (tolvaptan tablets).** Samsca is a tolvaptan product that is indicated for the treatment of clinically-significant hypervolemic and euvolemic hyponatremia, including patients with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH).[6] Concomitant use is not recommended.

2. **Hyponatremia.** Samsca is another tolvaptan product indicated for the treatment of clinically-significant hypervolemic and euvolemic hyponatremia (serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction and fluid restriction), including patients with heart failure and SIADH. Samsca should be used for this condition.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Jynarque® tablets [prescribing information]. Rockville, MD: Otsuka; October 2020.
2. Chapman AB, Devuyst O, Eckardt KU, et al. Autosomal-dominant polycystic kidney disease (ADPKD): executive summary from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. *Kidney Int*. 2015;88:17-27.
3. Ong ACM, Devuyst O, Knebelmann B, et al, on behalf of the ERA-EDTA Working Group for Inherited Kidney Diseases. Autosomal dominant polycystic kidney disease: the changing face of clinical management. *Lancet*. 2015;385:1993-2002.
4. Harris PC, Torres VE. Polycystic Kidney Disease, Autosomal Dominant. In Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2018. Last Updated: September 29, 2022. Available at: https://www.ncbi.nlm.nih.gov/books/NBK1246/ Accessed on June 20, 2024.
5. National Kidney Foundation. Polycystic kidney disease. Available at: https://www.kidney.org/atoz/content/polycystic. Accessed on June 20, 2024.
6. Samsca® tablets [prescribing information]. Rockville, MD: Otsuka; April 2021.
7. Muller RU, Messchendorp AL, Birn H, et al. An update on the use of tolvaptan for autosomal dominant polycystic kidney disease: Consensus statement on behalf of the ERA Working Group on Inherited Kidney Disorders, the European Rare Kidney Disease Reference Network and Polycystic Kidney Disease International. *Nephrol Dial Transplant*. 2022;37:825-839.
8. Polycystic Kidney Disease Foundation. Tolvaptan. Available at: https://pkdcure.org/tolvaptan/. Accessed on June 20, 2024.