VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/16/2021

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 (ESRD); 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-European Dialysis and Transplant Association (ERA-EDTA) Working Groups on Inherited Kidney Disorders and the European Renal Best Practice published a position statement regarding use of tolvaptan in ADPKD (2016).[7] A confirmed estimated glomerular filtration rate (eGFR) decline $\geq$ 5 mL/min/1.73 m^2 in 1 year, and/or $\geq$ 2.5 mL/min/1.73 m^2 per year over a period of 5 years defines rapid progression. Also, a total kidney volume increase > 5% per year by repeated measurements (preferably three or more, each at least 6 months apart and by magnetic resonance imaging) defines rapid progression.[7] The pivotal trials for Jynarque did not involve patients with Stage 5 chronic kidney disease (glomerular filtration rate [GFR] < 15 mL/min/1.73 m^2 or receiving dialysis).

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

Safety

Jynarque has a Boxed Warning regarding a risk of serious liver injury which can be fatal.[1] Monitor transaminases and bilirubin levels prior to therapy initiation, at 2 weeks and 4 weeks after initiation, then continuing monthly for the first 18 months and once every 3 months thereafter.

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 criteria:

FDA-Approved Indication

1. **Autosomal Dominant Polycystic Kidney Disease.** Approve for 1 year if the patient meets the following criteria (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 (e.g., reduced or declining renal function, high or increasing total kidney volume [height adjusted]); AND
   - **C)** Patient does not have Stage 5 chronic kidney disease (glomerular filtration rate < 15 mL/min/1.73 m^2 or receiving dialysis); AND
   - **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 syndrome of inappropriate antidiuretic hormone (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 for oral use [prescribing information]. Rockville, MD: Otsuka Pharmaceuticals; 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.
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5. National Kidney Foundation. Polycystic kidney disease. Available at: https://www.kidney.org/atoz/content/polycystic. Accessed on June 9, 2021.
6. Samsca® tablets [prescribing information]. Rockville, MD: Otsuka Pharmaceuticals; June 2018.
7. Gansevoort RT, Arici M, Benzing T, et al. Recommendations for the use of tolvaptan in autosomal dominant polycystic kidney disease: a position statement on behalf of the ERA-EDTA Working Groups on Inherited Kidney Disorders and European Renal Best Practice. *Nephrol Dis Transplant*. 2016;31:337-348.
8. Polycystic Kidney Disease Foundation. Tolvaptan. Available at: https://pkdcure.org/tolvaptan/. Accessed on June 9, 2021.