



Smart

PA

Clinical Edit Criteria

Drug/Drug Class: **Jynarque® (tolvaptan) oral tablets Clinical Edit**

Date: **April 11, 2019**

Prepared for:

Prepared by: **MO HealthNet**

New Criteria

Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Jynarque® (tolvaptan).

Jynarque® is a selective vasopressin V2-receptor antagonist indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD). Jynarque® decreases the rate of growth of total kidney volume and decrease the formation and enlargement of kidney cysts. Jynarque® should be used at patients who are at *high risk* for rapidly declining kidney function. Tolvaptan, the active ingredient in Jynarque®, is also marketed under the brand name Samsca with an indication to treat clinically significant hypervolemic and euvolemic hyponatremia. The use of Jynarque® requires prescribers to enroll in a Risk Evaluation and Mitigation Strategies (REMS) program due to its potential to cause severe liver injury including death. Due to the highly specific patient population that would benefit from treatment with Jynarque®, high cost, and risk of liver toxicity, MO HealthNet recommends adding a clinical edit to ensure appropriate patient selection.

Why was this Issue Selected:

The most common genetic cause of chronic kidney disease is ADPKD, affecting about 140,000 people in the United States. It has a reported prevalence of 1:400 to 1:1000 and affects all races. Annually in the United States, approximately 5% of patients who are started on dialysis have ADPKD as an underlying cause. The recommended initial dose of Jynarque® is 45mg on waking and 15mg taken 8 hours later. If tolerated, may be increased at weekly intervals to 60mg plus 30mg, then 90mg plus 30mg a day.

Program-specific information:

- Drug**
- Jynarque®

Cost per Month
\$13,040 WAC

Setting & Population:

Patients ages 18 years and older

Type of Criteria:

Increased risk of ADE

Clinical Edit

Appropriate Indications

Data Sources:

Only administrative databases

Databases + Prescriber-supplied

Setting & Population

- Drug for review: Jynarque® (tolvaptan)
- Age range: Patients ages 18 years and older
- Gender: Male and female

Approval Criteria

- 18 years or older
- Diagnosis of rapidly progressing ADPKD
- No history of liver disease
- No history of CYP-3A4 inhibitors in past 30 days
- Absence of other contraindications
- Baseline LFTs for initial approval, and every 3 months for re-authorizations

Denial Criteria

- Lack of appropriate Diagnosis
- Patients with eGFR of less than 25 ml/min
- Patients less than 18 years old
- Patients with liver impairment
- Patients who are breastfeeding

References

1. Chapman AB, Rahbari-Oskoui F, Bennett W. Course and treatment of autosomal dominant polycystic kidney disease. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> (Accessed on August 27, 2018).
2. Jynarque: Autosomal Dominant Polycystic Kidney Disease. <https://secure.ipdanalytics.com/User/Pharma/RxStrategy>