Washington State Health Care Authority

# Endocrine and Metabolic Agents: Vasopressin Receptor Antagonists – Oral

## Medical policy no. 30.45.40-1 Effective Date: 2/1/2026

### Related medical policies:

| Policy Number | Policy Name |
|---|---|
| N/A | |

***Note:*** *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

*To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx*

### Medical necessity

| Drug | Medical Necessity |
|---|---|
| tolvaptan (generic)<br>tolvaptan (Jynarque)<br>tolvaptan (Samsca) | **Vasopressin Receptor Antagonists** may be considered medically necessary in patients who meet the criteria described in the clinical policy below.<br><br>• Non-Preferred brand name products on the Apple Health Drug List with an A-rated generic, biosimilar or interchangeable biosimilar must also meet criteria in Non-Clinical Policy No 0001 (NC-001).<br><br>If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health. |

### Clinical policy:

| Clinical Criteria | |
|---|---|
| **Autosomal dominant polycystic kidney disease (ADPKD)**<br><br>tolvaptan (generic)<br>tolvaptan (Jynarque) | Tolvaptan may be approved when all the following documented criteria are met:<br><br>1. Prescribed by, or in consultation with, a nephrologist; **AND**<br>2. Diagnosis of autosomal dominant polycystic kidney disease including:<br>a. eGFR is $\geq$ 25ml/min per 1.73m$^2$ prior to starting tolvaptan; **AND** |

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| | b. Provider attests member is at risk of rapid disease progression (e.g. MAYO class 1C, 1D, or 1E)<br><br>If ALL criteria are met, the request will be authorized for **6 months.** |
| | **Criteria (Reauthorization)**<br>Tolvaptan may be approved when all the following documented criteria are met:<br><br>1. Documentation is submitted demonstrating decline in disease progression or a positive clinical response [e.g., decreased rate of GFR decline, slowed increase in total kidney volume].<br><br>If ALL criteria are met, the request will be authorized for **12 months.** |
| **Hyponatremia, Hypervolemic or euvolemic**<br><br>tolvaptan (generic)<br>tolvaptan (Samsca) | Tolvaptan may be approved when all the following documented criteria are met:<br><br>1. Patient is 18 years of age or older; **AND**<br>2. The medication was initiated in a hospital setting; **AND**<br>3. Diagnosis of hypervolemic or euvolemic hyponatremia (serum sodium <125mEq/L); **AND**<br>4. Provider attests that the patient does not have cirrhosis of the liver; **AND**<br>5. Total length of treatment will not exceed 30 days<br><br>If ALL criteria are met, the request will be authorized for **1 month** |
| | **Criteria (Reauthorization)**<br><br>Tolvaptan may be approved when all the following documented criteria are met:<br>1. The initial authorization criteria are met (1 through 5); **AND**<br>2. The episode of hyponatremia is a separate occurrence, distinct from any previous episode of hyponatremia.<br><br>If ALL criteria are met, the request will be authorized for **1 month** |

## Dosage and quantity limits

| Drug | Indication | Approved Dose | Dosage Form and Quantity Limit |
|---|---|---|---|
| **Tolvaptan (Jynarque, generic)** | ADKPD | **Initial dose:** 45 mg in morning and 15 mg 8 hours later<br><br>**Titration dose:** 60 mg in morning and 30 mg 8 hours later | • 15 mg tab: 1 tablet per day<br>• 30 mg tab: 1 tablet per day<br>• Dose packs: 56 tablets (1 carton) per 28 days |

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| | | **Target dose:** 90 mg in morning and 30 mg 8 hours later | |
| **Tolvaptan (Samsca, generic)** | Hyponatremia | 15 to 60 mg once daily | • 15 mg tab: 1 tablet per day<br>• 30 mg tab: 2 tablets per day |

## Coding:

| HCPCS Code | Description |
|---|---|
| N/A | |

## Background:

**Autosomal dominant polycystic kidney disease (ADPKD)**

ADPKD is an irreversible inherited disease that causes decline in kidney function and leads to kidney replacement in the majority of cases. Risk of progression varies and can be estimated using the Mayo classification system, which stratifies patients into classes (1A through 1E) based on patient characteristics (i.e. age, height, and total kidney volume). Classes 1C, 1D, and 1E are considered high-risk of progression to end-stage kidney disease. The Kidney Disease Improving Global Outcomes (KDIGO) 2025 Clinical Practice Guideline for the treatment of ADPKD recommends tolvaptan to delay the progression of kidney disease in patients at high-risk of progression. No other pharmacological treatments are recommended by the guideline to delay disease progression.

In its initial phase 3, double-blind, randomized controlled trial, tolvaptan (Jynarque) was evaluated against placebo in 1445 patients who had a creatinine clearance of 60ml/min or more. Annual rate of total kidney volume increased 2.8% in the tolvaptan group compared to 5.5% in the placebo group ($p<0.001$). Similarly, time to clinical progression (defined as worsening kidney function, kidney pain, hypertension, or albuminuria) favored the tolvaptan group. A subsequent clinical trial studied individuals with an eGFR from 25 to 65 ml/min/1.73m$^2$ and demonstrated that tolvaptan slowed the rate of eGFR decline compared to placebo (-2.34 ml/min/1.73m$^2$ vs -3.61 ml/min/1.73m$^2$, $P<0.001$).

Due to the high risk for severe liver damage, Jynarque is strictly controlled by a Risk Evaluation and Mitigation Strategy (REMs) which requires comprehensive laboratory monitoring and enrollment by prescribers and pharmacies.

**Hyponatremia, Hypervolemic or euvolemic**

Moderate to severe hyponatremia, a potentially life-threatening condition defined as a serum sodium level of less than 130mEq/L, results from an imbalance of water relative to sodium. Common causes include polydipsia, syndrome of inappropriate antidiuretic hormone secretion (SIADH), heart failure, cirrhosis, and advanced kidney failure. Standard of care involves inpatient management, including infusion of 3% saline solution with or without diuretics depending on underlying cause. Sodium levels are carefully monitored to prevent a correction that is too rapid. Tolvaptan may be used in addition to, or instead of 3% saline. Tolvaptan is not indicated to correct sodium levels in hypovolemic hyponatremia, commonly caused by dehydration, and is contraindicated in the setting of liver failure.

## References

1. Jynarque [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceutical, Inc., October 2020

2. Samsca [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceutical, Inc., April 2021.
3. Kidney Disease: Improving Global Outcomes (KDIGO) ADPKD Work Group. Kdigo 2025 clinical practice guideline for the evaluation, management, and treatment of autosomal dominant polycystic kidney disease(Adpkd). *Kidney Int*. 2025;107(2S):S1-S239.
4. Torres VE, Chapman AB, Devuyst O, et al. Tolvaptan in patients with autosomal dominant polycystic kidney disease. *N Engl J Med*. 2012;367(25):2407-2418.
5. Torres VE, Chapman AB, Devuyst O, et al. Tolvaptan in later-stage autosomal dominant polycystic kidney disease. *N Engl J Med*. 2017;377(20):1930-1942.

## History

| Approved Date | Effective Date | Version | Action and Summary of Changes |
|---|---|---|---|
| 08/13/2025 | 02/01/2026 | 30.45.40-1 | Approved by DUR Board<br>-New policy created |