

DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Tolvaptan Products Drug Quantity Management Policy – Per Rx

- Jynarque® (tolvaptan tablets – Otsuka America)
- Samsca® (tolvaptan tablets – Otsuka America, generic)

REVIEW DATE: 05/04/2022

OVERVIEW

Tolvaptan products, Samsca (generic) and Jynarque, are selective vasopressin V2-receptor antagonists.^{1,2}

Samsca (generic) is indicated for the treatment of **clinically significant hypervolemic and euvoletic hyponatremia** (serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure, cirrhosis and Syndrome of Inappropriate Antidiuretic Hormone (SIADH).¹

Jynarque is indicated to slow kidney function decline in adults at risk of rapidly progressing **autosomal dominant polycystic kidney disease** (ADPKD).² Jynarque is available through a restricted distribution program under a Risk Evaluation and Mitigation Strategy (REMS) because of the risks of liver injury.

Dosing

Samsca (generic) should be initiated and re-initiated in a hospital to evaluate therapeutic response and because too rapid of a correction of hyponatremia can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death.¹ The usual starting dose of Samsca is 15 mg once daily (QD). The dose is increased to 30 mg QD, after at least 24 hours, to a maximum of 60 mg QD, as needed to achieve the desired level of serum sodium. Samsca is not to be administered for > 30 days to minimize the risk of liver injury.

The initial dosage for Jynarque is 60 mg per day, taken as 45 mg upon waking and 15 mg taken 8 hours later (“45 mg + 15 mg”).² The dose is titrated to 60 mg + 30 mg then to 90 mg + 30 mg per day if tolerated with at least weekly intervals between titrations. Patients may down-titrate based on tolerability. In patients taking concomitant moderate cytochrome P450(CYP)3A inhibitors, the dose of Jynarque is reduced (refer to Table 1). Consider further reductions if the patient cannot tolerate the reduced dose. Interrupt Jynarque temporarily for short-term therapy with moderate CYP3A inhibitors if the recommended reduced doses are not available.

Table 1. Jynarque Dose Adjustments for Patients Taking Moderate CYP3A Inhibitors.²

Standard Morning and Afternoon Dose	Dose with Moderate CYP3A Inhibitors
90 mg and 30 mg	45 mg and 15 mg
60 mg and 30 mg	30 mg and 15 mg
45 mg and 15 mg	15 mg and 15 mg

CYP – Cytochrome P450.

Availability

Samsca (generic) is available as 15 mg and 30 mg tablets in blister packs of 10 tablets; additionally, the generic 30 mg tablets are available in bottles of 10 tablets.¹

Jynarque is available as 15 mg and 30 mg tablets in bottles of 30 tablets.² In addition, Jynarque is available in 7-day blister packs (containing 14 tablets) in 15 mg/15 mg, 30 mg/15 mg, 45 mg/15 mg, 60 mg/30 mg, 90 mg/30 mg tablet strengths.²

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of tolvaptan products. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per Rx
Samsca® (tolvaptan tablets, generic)	15 mg tablets	30 tablets
	30 mg tablets	60 tablets
Jynarque® (tolvaptan tablets)	15 mg tablets	120 tablets
	30 mg tablets	120 tablets
	15/15 mg tablets (7-day blister card)	56 tablets
	30/15 mg tablets (7-day blister card)	56 tablets
	45/15 mg tablets (7-day blister card)	56 tablets
	60/30 mg tablets (7-day blister card)	56 tablets
	90/30 mg tablets (7-day blister card)	56 tablets

CRITERIA

Samsca 15 mg tablets (generic)

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (e.g., the dose requires multiple same strength tablets be used AND would otherwise require two strengths to be used), approve 90 tablets per dispensing.

Samsca 30 mg tablets (generic)

No overrides recommended.

Jynarque 15 mg tablets

No overrides recommended.

Jynarque 30 mg tablets

No overrides recommended.

Jynarque 15 mg/15 mg tablet 7-day blister pack

No overrides recommended.

Jynarque 30 mg/15 mg tablet 7-day blister pack

No overrides recommended.

Jynarque 45 mg/15 mg tablet 7-day blister pack

No overrides recommended.

Jynarque 60 mg/30 mg tablet 7-day blister pack

No overrides recommended.

Jynarque 90 mg/30 mg tablet 7-day blister pack

No overrides recommended.

REFERENCES

1. Samsca® tablets [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical; April 2021.
2. Jynarque® tablets [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical; October 2020.