



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: 05/15/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 euvolemic 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 therapy temporarily for short-term use 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

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

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Samsca®	15 mg tablets	30 tablets	90 tablets
	30 mg tablets	60 tablets	180 tablets

(tolvaptan tablets, generic)			
Jynarque® (tolvaptan tablets)	15 mg tablets	120 tablets	360 tablets
	30 mg tablets	120 tablets	360 tablets
	15/15 mg tablets (7-day blister card)	56 tablets	168 tablets
	30/15 mg tablets (7-day blister card)	56 tablets	168 tablets
	45/15 mg tablets (7-day blister card)	56 tablets	168 tablets
	60/30 mg tablets (7-day blister card)	56 tablets	168 tablets
	90/30 mg tablets (7-day blister card)	56 tablets	168 tablets

Tolvaptan Products Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

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 at retail or 270 tablets per dispensing at home delivery.

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

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	05/04/2023
Annual Revision	No criteria changes.	05/15/2024

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