Samsca

Description

Samsca (tolvaptan)

Background
Samsca (tolvaptan) is a selective vasopressin (V2-receptor) antagonist, which increases urine water excretion. The extra excretion of water in the urine increases serum sodium concentrations in the blood. Samsca (tolvaptan) is used clinically to treat hyponatremia, which is low serum sodium concentrations. Hyponatremia can be caused by many disease states, including heart failure and SIADH syndrome of inappropriate antidiuretic hormone secretion (SIADH) (1-2).

Regulatory Status
FDA approved indication: Samsca is a selective vasopressin V2-receptor antagonist 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 and syndrome of inappropriate antidiuretic hormone (SIADH) (1).

Limitations of use:
Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with Samsca. It has not been established that Samsca provides a symptomatic benefit to patients (1).

Samsca carries a boxed warning that patients should be initiated and re-initiated only in a hospital where serum sodium can be monitored closely. Also because of the risk of hepatotoxicity, tolvaptan should not be used for autosomal dominant polycystic kidney disease (ADPKD) outside of the FDA-Approved REMS (1).
<table>
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<th>Section:</th>
<th>Prescription Drugs</th>
<th>Effective Date:</th>
<th>January 1, 2020</th>
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<tr>
<td>Subsection:</td>
<td>Endocrine and Metabolic Drugs</td>
<td>Original Policy Date:</td>
<td>June 1, 2018</td>
</tr>
<tr>
<td>Subject:</td>
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There is an additional boxed warning in the package insert addressing the risk of osmotic demyelination due to too rapid correction of hyponatremia (e.g. 12 mEq/L/24 hours). Therefore, initiation and re-initiation of this medication should only be done in hospital where serum sodium can be monitored closely (1).

Samsca should not be used for longer than 30 days due to possible liver injury leading to organ transplant or death. Long-term tolvaptan treatment (mean duration of treatment of 0.75 years) had no demonstrated effect, either favorable or unfavorable, on all-cause mortality [HR (95% CI): 0.98 (0.9, 1.1)] or the combined endpoint of CV mortality or subsequent hospitalization for worsening HF (1-2).

The safety and effectiveness of Samsca in pediatric patients have not been established (1).

### Related policies
- Jynarque

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### Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Samsca may be considered **medically necessary** for patients 18 years and older for the treatment of euvolemic or hypervolemic hyponatremia and if the conditions indicated below are met.

Samsca may be considered **investigational** in patients less than 18 years of age and for all other indications.

### Prior-Approval Requirements

**Age**
- 18 years of age and older

**Diagnosis**
- Patient must have the following:
  - Euvolemic or hypervolemic hyponatremia
AND ALL of the following:
1. Medication **HAS** or **WILL BE** initiated in the hospital where serum sodium can be monitored closely

AND NONE of the following:
1. Used for the treatment of autosomal dominant polycystic kidney disease (ADPKD)
2. Used for hypovolemic hyponatremia
3. Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms
4. Significant liver disease (including cirrhosis)
5. Anuria
6. Dual therapy with Jynarque (tolvaptan)

Prior–Approval **Renewal** Requirements

**Age**
18 years of age and older

**Diagnosis**

Patient must have the following:

Euvolemic or hypervolemic hyponatremia

AND ALL of the following:
1. Medication **HAS** or **WILL BE** initiated in the hospital where serum sodium can be monitored closely
2. There has been at least a 30 day lapse between the last course of therapy and this course of therapy

AND NONE of the following:
1. Used for the treatment of autosomal dominant polycystic kidney disease (ADPKD)
2. Used for hypovolemic hyponatremia
3. Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms
5. Significant liver disease (including cirrhosis)
6. Anuria
6. Dual therapy with Jynarque (tolvaptan)

**Policy Guidelines**

**Pre–PA Allowance**
None

**Prior–Approval Limits**

**Quantity**

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity per 30 days</th>
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<tr>
<td>15 mg</td>
<td>120 tablets per 30 days</td>
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<td>30 mg</td>
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**Duration**
1 month (30 days)

**Prior–Approval Renewal Limits**
Same as above

**Rationale**

**Summary**
Samsca (tolvaptan) is a selective vasopressin (V2-receptor) antagonist, which increases urine water excretion. The extra excretion of water in the urine increases serum sodium concentrations in the blood. Samsca 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 and syndrome of inappropriate antidiuretic hormone (SIADH). Per the FDA drug safety communication from April 30, 2013, Samsca should not be used for longer than 30 days due to possible liver injury leading to organ transplant or death (1-2).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Samsca while maintaining optimal therapeutic outcomes.
References
2. FDA Drug Safety Communication: FDA limits duration and usage of Samsca (tolvaptan) due to possible liver injury leading to organ transplant or death. Announcement date: April 30, 2013.

Policy History
<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>June 2018</td>
<td>Addition to PA</td>
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<tr>
<td>September 2018</td>
<td>Annual review and reference update</td>
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<tr>
<td></td>
<td>Addition of no dual therapy with Jynarque per SME</td>
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<tr>
<td>December 2019</td>
<td>Annual review</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.