

Pharmacy Policy

Samsca/tolvaptan[®]

Policy Number: 9.319

Version Number: 2.0

Version Effective Date: 9/1/2021

Product Applicability All Plan+ Products

Well Sense Health Plan

New Hampshire Medicaid

Boston Medical Center HealthNet Plan

MassHealth - MCO

MassHealth - ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Samsca 15mg
- Tolvaptan 15 mg
- Samsca 30 mg
- Tolvaptan 30 mg

The Plan may authorize coverage of the above products for members meeting the following criteria:

| | |
|-------------------------------------|---|
| Covered Use | All FDA approved indications unless otherwise excluded |
| Required Medical Information | <ol style="list-style-type: none"> 1. A diagnosis of clinically significant hypervolemic or euvoletic hyponatremia; AND 2. One of the following (lab values within the last 7 days is required): <ul style="list-style-type: none"> • Serum sodium less than 125 mEq/L • Serum sodium level equal to or greater than 125 but patient is symptomatic and |

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

| | |
|---------------------------|--|
| | <p>has resisted correction with fluid restriction; AND</p> <p>3. Therapy has been initiated or reinitiated in the hospital within the last 30 days (hospital record must be provided); AND</p> <p>4. For brand Samsca 30 mg, clinical reason why member cannot use generic tolvaptan</p> |
| Age Restrictions | <ul style="list-style-type: none"> ▪ 18 years of age or older |
| Coverage Duration | <ul style="list-style-type: none"> ▪ 1 month |
| Quantity Limit (?) | <ul style="list-style-type: none"> ▪ Samsca 15 mg tablet – 30 tablets per 30 days ▪ Tolvaptan 30 mg tablet – 60 tablets per 30 days |

Clinical Background Information and References

1. Product Information. Samsca® (tolvaptan) tablets for oral use. Otsuka Pharmaceutical Co., Ltd, Tokyo, 101-8535 Japan. April, 2018.
2. Sterns RH. Treatment of hyponatremia: Syndrome of inappropriate antidiuretic hormone secretion (SIADH) and reset osmostat. UpToDate. Last updated May 8, 2017. Available: www.uptodate.com. Accessed June 19, 2018.
3. U.S. Food and Drug Administration. FDA Drug Safety Communication: FDA Limits Duration and Usage of Samsca (tolvaptan) Due To Possible Liver Injury Leading to Organ Transplant or Death. Accessed 6/9/2014. <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM350084.pdf>

| Original Approval Date | Original Effective Date | Policy Owner | Approved by |
|------------------------|-------------------------|-------------------|---|
| 12/1/2020 | 1/1/2021 | Pharmacy Services | Pharmacy & Therapeutics (P&T) Committee |

| Policy Revisions History | | | |
|--------------------------|--|-------------------------|---------------|
| Review Date | Summary of Revisions | Revision Effective Date | Approved by |
| 12/1/2020 | 9.171 Samsca Policy retired, new policy created | 1/1/2021 | P&T Committee |
| 5/13/2021 | P&T Review: Updated initial criteria for sodium level and added generic tolvaptan to formulary with PA | 9/1/2021 | P&T Committee |

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Next Review Date

5/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

* *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.