I. Medication Description

Tolvaptan is an oral non-peptide V2 vasopressin receptor antagonist indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (i.e., serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including in patients with heart failure, cirrhosis, and syndrome of inappropriate antidiuretic hormone (SIADH). Tolvaptan is initiated and re-initiated in a hospital and then continued on an outpatient basis, and has been shown to induce short-term clinical improvements but has not demonstrated improvement in long-term outcomes such as mortality or hospitalizations.

II. Position Statement

Coverage is provided immediately for up to 30 days of therapy per each rolling 365 days. Specific quantity limits are outlined below.

Coverage is determined through a prior authorization process with supporting clinical documentation for all requests that exceed these limits.

III. Policy

Coverage of up to one month of therapy does not require preauthorization.

IV. Quantity Limitations

Coverage will be limited to a quantity of thirty 15mg tablets or up to sixty 30mg tablets over a one-month treatment period.

V. Coverage Duration

Coverage is available for up to 30 days per each rolling 365 day period.

VI. Coverage Renewal Criteria

Additional coverage for treatment beyond 30 days is provided through prior authorization in accord with the following:

- Samsca was initiated in a hospital (where serum sodium could be monitored closely) AND
- The patient is symptomatic AND
- The patient has a serum sodium less than or equal to 125mEq/L AND
• The patient requires ongoing treatment to prevent clinically significant hypervolemic or euvolemic hyponatremia due to conditions such as heart failure, cirrhosis or SIADH AND
• Hyponatremia cannot be controlled with fluid restriction and correction of underlying conditions.

VII. Billing/Coding Information

Available as 15mg and 30mg tablets

VIII. Summary of Policy Changes

• 9/15/12: Criteria for coverage changed to symptomatic hyponatremia with serum sodium less than 125mEq/L.
• 9/15/13: Addition of warnings and evaluation of liver injury for renewal of treatment
• 9/15/14: limit to 30 days of total therapy based on prescribing information warnings; specific criteria in place for exceeding these limits.
• 6/15/15: no policy changes
• 7/1/15: formulary distinctions made
• 6/15/16: no policy changes
• 4/5/17: no policy changes
• 5/1/18: no policy changes

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.