BlueCross BlueShield Federal Employee Program

SAMSCA (tolvaptan)

RATIONALE FOR INCLUSION IN PA PROGRAM

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 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) (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).

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 had no demonstrated effect, either favorable or unfavorable (1-2).

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

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

1. Samsca [package insert]. Rockville, MD. Otsuka America Pharmaceutical, Inc.; April 2021.
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.