

PHARMACY POLICY STATEMENT North Carolina Marketplace

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| DRUG NAME | Zorbtive (somatropin) |
| BENEFIT TYPE | Pharmacy |
| STATUS | Prior Authorization Required |

Zorbtive is a human growth hormone initially approved by the FDA in 2009. It is indicated for the treatment of Short Bowel Syndrome in patients receiving specialized nutritional support. Per the AGA guidelines, the use of Zorbtive has largely been discontinued due to unacceptable side effects and questionable long-term efficacy.

Zorbtive (somatropin) will be considered for coverage when the following criteria are met:

Short Bowel Syndrome

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a diagnosis of short bowel syndrome, confirmed by <200cm small intestine length; AND
4. Zorbtive will be used with specialized nutritional support; AND
5. Member has been dependent on parenteral nutrition for more than 12 months; AND
6. Member does not have active malignancy.
7. **Dosage allowed/Quantity limit:** Administer 0.1 mg/kg subcutaneously once daily to a maximum daily dose of 8 mg for 4 weeks. Quantity Limit: 30 vials per 30 days

If all the above requirements are met, the medication will be approved for 4 weeks.

For **reauthorization**:

Will not be reauthorized for continuous use.

CareSource considers Zorbtive (somatropin) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|------------|----------------------------------|
| 11/10/2022 | New policy for Zorbtive created. |

References:

1. Zorbtive [Prescribing Information]. Rockland, MA: EMD Serono Inc.; May 2017
2. Iyer K et al. AGA Clinical Practice Update on Management of Short Bowel Syndrome: Expert Review. *Clinical Gastroenterology and Hepatology*; 2022; 20(10): 2185-2194

3. Byrne T.A. et al Growth hormone, glutamine, and an optimal diet reduces parenteral nutrition in patients with short bowel syndrome: a prospective, randomized, placebo-controlled, double-blind clinical trial. *Ann Surg.* 2005; 242: 655-661

Effective date: 07/01/2023

Revised date: 11/10/2022