



**Prior Authorization Approval Criteria**  
*Department of Pharmacy Services*

**Generic Name:** somatropin

**Brand Name:** Zorbtive

**Medication Class:** Human Growth Hormone

**FDA Approved Uses:** treatment of Short Bowel Syndrome (SBS) in patients receiving specialized nutritional support.

Note: specialized nutritional support may consist of a high carbohydrate, low-fat diet, adjusted for individual patient requirements and preferences.

**Usual Dose:** 0.1 mg/kg subcutaneously daily to a maximum of 8mg daily.

**Duration of Therapy:** 4 weeks

Note: administration for greater than 4 weeks has not been adequately studied.

**Criteria for Use:** *(bullet points below are all inclusive unless otherwise noted)*

- Clinically diagnosed SBS
    - <200cm of small intestine (jejunum and ileum)
    - <50 to 70cm of small intestine and intact colon
    - <100 10 150 cm of small intestine after resection of the colon.
  - Patients receiving specialized nutritional support such as intravenous parenteral nutrition (IPN).
  - Must be used in conjunction with optimal management for SBS.  
Note- Optimal management of SBS may include dietary adjustments, enteral feedings, parenteral nutrition, fluid and micronutrient supplements as needed.
  - At least two months post-resection, and stable.
  - Ability to ingest some food.
  - Intact stomach and duodenum.
  - 30% or better functioning colon with at least 15cm intact jejunum and/or ileum.
- OR
- Less than 30% functioning colon, with at least 90 cm intact jejunum and/or ileum.
  - Dietary modifications must be made 2 weeks prior to beginning Zorbtive treatment.

**Contraindications:**

- Should not be initiated in patients with acute critical illnesses due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure.
  - Known sensitivity to benzyl alcohol
  - Known hypersensitivity to growth hormone.
  - Active neoplasia
  - Concomitant anti-tumor therapy
- \*note- any tumor therapy should be completed prior to starting therapy with Zorbtive



**Not Approved if:**

- Patient has any contraindications to the use of somatropin
- Patient does not meet the above stated criteria.
- Patient is malnourished.
- Hepatic and Renal status is not stable based on lab values as follows:
  - Total serum bilirubin > 3 times the upper limit of normal
  - Serum creatinine level  $\geq$  3 mg/dl.
- Hgb, Hct and electrolytes are unstable.

**Special Considerations:**

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_

