

SPECIALTY GUIDELINE MANAGEMENT

ZORBTIVE (somatropin)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Zorbtive is indicated for the treatment of short bowel syndrome in patients receiving specialized nutritional support. Zorbtive should be used in conjunction with optimal management of short bowel syndrome.

All other indications are considered experimental/investigational and are not a covered benefit.

II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a gastroenterologist or nutritional support specialist.

III. CRITERIA FOR INITIAL APPROVAL

A. Short bowel syndrome (SBS)

Authorization of a lifetime total of 8 weeks may be granted for members who are prescribed Zorbtive in conjunction with optimal management of SBS.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

VI. REFERENCES

1. Zorbtive [package insert]. Rockland, MA: EMD Serono, Inc.; January 2012.