A. SUBJECT

Short Bowel Syndrome
- Gattex (teduglutide (rDNA origin) for injection)
- Zorbtive (somatropin (rDNA origin) for injection)

B. BACKGROUND

The intent of CareSource Pharmacy Policy Statements is to encourage appropriate selection of patients for therapy according to product labeling, clinical guidelines, and/or clinical studies as well as to encourage use of preferred agents. The CareSource Pharmacy Policy Statement is a guideline for determining health care coverage for our patients with benefit plans covering prescription drugs. Pharmacy Policy Statements are written on selected prescription drugs requiring prior authorization or step therapy. The Pharmacy Policy Statement is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

C. DEFINITIONS

N/A

D. POLICY

I. CareSource will approve the use of Zorbtive and consider its use as medically necessary when ALL of the following criteria have been met:
   a. Diagnosis of short bowel syndrome. Please submit chart documentation.
   b. Patient is 18 years of age or older.
   c. Prescribed by a gastroenterologist or nutritional support specialist.
d. Used in conjunction with specialized nutritional support (examples: high complex-carbohydrate, low-fat diet, TPN, IPN, PPN, rehydration solutions, electrolyte replacement).
e. Patient has not previously received Zorbive therapy for longer than 4 weeks.

II. CareSource will approve the use of Gattex and consider its use as medically necessary when ALL of the following criteria have been met:
  a. Diagnosis of short bowel syndrome. Please submit chart documentation.
  b. Patient is 18 years of age or older.
  c. Prescribed by a gastroenterologist or nutritional support specialist.
  d. Patient has been dependent on parenteral nutrition support for at least 12 months with parenteral nutrition occurring at least three times per week

Note: Documented diagnosis must be confirmed by portions of the individual’s medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but are not limited to, test reports, chart notes from provider’s office, or hospital admission notes.

ALL other uses of Zorbive and Gattex are considered experimental/investigational, and therefore, will follow CareSource’s Off-Label policy.

Refer to the product package insert for dosing, administration and safety guidelines.

For Medicare Plan members, reference Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD). If there is no NCD or LCD present, reference the CareSource Policy for coverage.

CONDITIONS OF COVERAGE
PLACE OF SERVICE
Office, Outpatient, Home
**Preferred place of service is in the home.
This medication can be self-administered and can be billed through the pharmacy benefit.

Note: CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective settings that are supportive of the patient’s medical condition(s) and unique needs and condition(s). The decision on the most appropriate setting for administration is based on the member’s current medical condition(s) and any required monitoring or additional services that may coincide with the delivery of the specific medication.

HCPCS
CPT

Step Therapy
Under some plans, including plans that use an open or closed formulary, some of the medications in this policy may be subject to step-therapy. Refer to the CareSource formulary tool or PDL for further guidance.

AUTHORIZATION PERIOD
Zorbive authorization period is 4 weeks. Zorbive is not eligible for reauthorization.

Gattex initial authorizations are valid for 6 months. Continued treatment may be considered when the member has shown biological response to Gattex supported by a 20% or more decrease in
the need for parenteral nutrition and documentation of a colonoscopy, or alternate imaging, within the first 6 months of treatment. A reauthorization after a successful initiation period will be placed for 6 months. **ALL** authorizations are subject to continued eligibility.

**E. RELATED POLICIES/RULES**

**F. REVIEW/REVISION HISTORY**

Date Issued: 08/01/2013  
Date Reviewed: 08/01/2013, 09/26/2014, 09/08/2015  
Date Revised: 09/08/2015 – added details on specialized diet & parenteral support, modified duration of Zorbitive approval  
10/04/2016 – Updated prescribers, added 4 weeks duration to previous Zorbitive trial, changed reauthorization period for Gattex, updated references

**G. REFERENCES**


**The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.**

Independent Medical Review - 12/20/2013