MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
08/01/2013	09/08/2017	10/04/2016

Policy Name	Policy Number
Short Bowel Syndrome (Gattex, Zorbtive)	SRx-0038

Policy Type		
☒ Pharmacy	☐ Administrative	☐ Payment

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

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 Zorbtive 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 Zorbtive 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
Zorbitive authorization period is 4 weeks. Zorbtive 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 Zorbtive approval 10/04/2016 – Updated prescribers, added 4 weeks duration to previous Zorbtive trial, changed reauthorization period for Gattex, updated references

G. REFERENCES

1. Gattex [package insert]. Bedminster, NJ: NPS Pharmaceuticals; July 2016.
2. Zorbitive [package insert]. Rockland, MA. EMD Serono, Inc. January 2012.
3. Nightingale J and Woodward JM. Guidelines for Management of patients with a Short Bowel. Gut. Aug 2006; 55(Supple 4):iv1-iv12.
4. Byrne TA, Morrissey TB, Nattakom TV, et al. Growth hormone, glutamine, and a modified diet enhance nutrient absorption in patients with short-bowel syndrome. J Parenter Enteral Nutr. 1995;19:296-302.
5. Byrne TA, Persinger RL, Young LS, et al. A new treatment for patients with short-bowel syndrome. Growth hormone, glutamine, and a modified diet. Ann Surg. 1995;222:243-255.
6. Sequy D, Vahedi K, Kapel N, et al. Low-dose growth hormone in adult home parenteral nutrition dependent short bowel syndrome patients: a positive study. Gastroenterol. 2003;1 24:293-302.
7. Jeppesen P, Pertkiewicz M, Messing B, et al. Teduglutide reduces need for parenteral support among patients with short bowel syndrome with intestinal failure. Gastroenterol. 2012; 143: 1473-1481.

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