



## MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
08/01/2013	09/08/2016	09/08/2015
Policy Name	Policy Number	
Short Bowel Syndrome (Gattex, Zorbitive)	SRx-0038	

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**
- **Zorbitive**

### B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the **Short Bowel Syndrome (PA)** Program is to encourage appropriate selection of patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

### C. DEFINITIONS

N/A

### D. POLICY

CareSource will approve the use of **Zorbitive** or **Gattex** and consider its use as medically necessary when **ALL** of the following criteria have been met for:

- Short Bowel Syndrome on parenteral support

Prior Authorization Criteria:

#### I. **Zorbitive**

- A. Documented diagnosis of Short Bowel Syndrome
- B. Used with in conjunction with special diet (may consist of a high carbohydrate, low



-fat diet, adjusted for individual patient requirements and preferences) and glutamine supplementation

- C. Patient is currently dependent upon parenteral nutrition or enteral feedings
- D. Medication is prescribed by a gastroenterologist
- E. Patient is 18 years of age or older
- F. Patient has not taken Zorbitive previously

## II. Gattex

- A. Documented diagnosis of Short Bowel Syndrome
- B. Age 18 years or older
- C. Medication is prescribed by a gastroenterologist
- D. Dependence on parenteral support for the last 12 months with parenteral nutrition occurring at least **3 (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 Zorbitive 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

Approved 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. A reauthorization after a successful initiation period

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will be placed for 1 year. **ALL** authorizations are subject to continued eligibility. Zorbitive authorization period is 4 weeks. Zorbitive is not eligible for reauthorization.

#### **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

#### **G. REFERENCES**

1. Gattex [package insert]. Bedminster, NJ: NPS Pharmaceuticals; June 2014.
2. Wolters Kluwer. Facts & Comparisons. [www.factsandcomparisons.com](http://www.factsandcomparisons.com)
3. U.S. Food and Drug Administration Drug Safety Communication. <http://www.fda.gov/downloads/Drugs/DrugSafety/ucm085930.pdf>
4. MCG Ambulatory Care 19th Edition, Copyright © 2015 MCG Health, LLC
5. Zorbitive [package insert]. Rockland, MA. EMD Serono, Inc. March 2012.

This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

**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

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