Pharmacy Policy Bulletin: J-0172 Gattex (teduglutide) – Commercial and Healthcare Reform	
Number: J-0172	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Healthcare Reform**: Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0172-017	**Original Date:** 03/06/2013
Effective Date: 02/14/2025	**Review Date:** 01/29/2025

Drugs Product(s):	• Gattex (teduglutide)
FDA-Approved Indication(s):	• Treatment of adult and pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

Background:	• Gattex (teduglutide) is a glucagon-like peptide-2 (GLP-2) analog that binds to GLP-2 receptors located in the intestine. • GLP-2 is secreted by the L- cells of the distal intestine after food digestion and causes local release of mediators such as insulin like growth factor (IGF)-1, nitric oxide, and keratinocyte growth factor (KGF). GLP-2 is known to increase intestinal blood flow, inhibit gastric acid secretion, reduce gastric motility, and increase intestinal barrier function. The combination of these effects may increase nutrient and fluid absorption in the intestine. • Short bowel syndrome (SBS) occurs when a reduced functional intestinal surface area causes poor absorption of nutrients. This reduced intestinal surface area is usually a result of surgical removal of portions of the small intestine. • Gattex is only FDA-approved in patients who are dependent on parenteral support. After taking Gattex, some patients may achieve enteral autonomy and may no longer require parental nutrition support. However, there is insufficient (and conflicting) evidence surrounding the safety and effectiveness of Gattex in these patients. It is unclear whether Gattex results in lasting changes to intestinal health, or if continued treatment with Gattex is required to maintain enteral autonomy. • Prescribing Considerations: ○ Gattex should be prescribed by a gastroenterologist. Prescribers of Gattex must complete the requirements of the Gattex REMS program. ○ Use of the Gattex 5 mg kit is not recommended in pediatric patients weighing less than 10 kg. ○ Gattex has a warning for acceleration of neoplastic growth. Within 6 months prior to initiating treatment with Gattex, adults should perform a colonoscopy with removal of polyps. Pediatric patients should perform fecal occult blood

	testing. If there is unexplained blood in the stool, a colonoscopy/sigmoidoscopy should be performed for pediatric patients. In both adult and pediatric patients, a colonoscopy is recommended after 1 year of treatment. ○ Laboratory assessments are recommended every 6 months. If any clinically meaningful elevation is seen, further diagnostic workup is recommended as clinically indicated (i.e., imaging of the biliary tract, liver, or pancreas)

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Gattex may be approved when one (1) of the following criteria is met **(A. or B.)**:

A. The member is 18 years of age or older and meets all of the following criteria **(1. through 4.)**:
- **1.** The member has a diagnosis of short bowel syndrome (no ICD-10 code).
- **2.** The member has been dependent on parenteral/intravenous nutrition support for at least 12 months.
- **3.** The member requires parenteral/intravenous nutrition at least three (3) times per week.
- **4.** The prescriber attests that a colonoscopy of the entire colon, with removal of polyps, was complete within 6 months prior to initiation of therapy.

B. The member is between 1 year and 17 years of age and meets all of the following criteria **(1. through 4.)**:
- **1.** The member weighs at least 10 kg.
- **2.** The member has a diagnosis of short bowel syndrome (no ICD-10 code).
- **3.** The member has been dependent on parenteral/intravenous nutrition for at least 12 months.
- **4.** The prescriber attests that a fecal occult blood test was performed within 6 months prior to initiation of therapy.

II. Reauthorization

When a benefit, reauthorization of Gattex may be approved when all of the following criteria are met **(A. and B.)**:

A. The member has experienced a reduction of at least 20% in parenteral nutrition/intravenous support volume from baseline.

B. The member meets one (1) of the following criteria **(1. or 2.)**:
- **1.** The member continues to be dependent on parenteral/intravenous nutrition support.
- **2.** The member is not receiving parenteral/intravenous nutrition support and meets the following criterion **(a.)**:
  - **a.** The member experienced therapeutic failure when Gattex was discontinued (specifically, the member had achieved enteral autonomy while taking Gattex and required re-introduction of parenteral/intravenous nutrition after discontinuing Gattex).

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Short bowel syndrome (SBS) is defined as < 200 cm of functional small bowel.

II. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

III. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.
    - *For Delaware Commercial fully-insured and ACA members, a 12 month authorization must be granted pursuant to 18 Del. C. §§3376(a) and 3586(a) and market conduct examination docket #5467.*

Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Gattex [package insert]. Lexington, Massachusetts: Shire-NPS Pharmaceuticals; February 2024.
2. Jeppesen PB, Pertkiewicz M, Messing B, et al. Teduglutide reduces need for parenteral support among patients with short bowel syndrome with intestinal failure. *Gastroenterology*. 2012; 143: 1473–1481.
3. Jeppesen PB, Gilroy R, Pertkiewicz M, et al. Randomised placebo-controlled trial of teduglutide in reducing parenteral nutrition and/or intravenous fluid requirements in patients with short bowel syndrome. *Gut*. 2011; 60: 902–914.
4. Gigola F, Cianci MC, Cirocchi R, et al. Use of Teduglutide in Children With Intestinal Failure: A Systematic Review. *Front Nutr*. 2022 Jun 14;9:866518.