

## PHARMACY POLICY STATEMENT

### Indiana Medicaid

<b>DRUG NAME</b>	<b>Gattex (teduglutide)</b>
<b>BENEFIT TYPE</b>	Pharmacy
<b>STATUS</b>	Prior Authorization Required

Gattex, approved by the FDA in 2012, is a glucagon-like peptide-2 (GLP-2) analog indicated for the treatment of adults and pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

SBS can result from a variety of different conditions that require surgical removal of portions of the small intestine including Crohn's disease, cancer, and vascular events. Many patients with SBS cannot absorb nutrients from food sources and need to be on parenteral support. Long-term parenteral support can negatively impact patients' quality of life.

Approval for Gattex was based on a clinical response defined as achieving at least 20% reduction in weekly parenteral nutrition/intravenous volume from baseline. At week 24, the mean reduction in weekly parenteral nutrition/intravenous volume was significant at 4.4 liters for Gattex-treated patients versus 2.3 liters for placebo-treated patients.

Gattex (teduglutide) will be considered for coverage when the following criteria are met:

#### Short Bowel Syndrome (SBS)

For **initial** authorization:

1. Member is at least 1 year of age (must weigh at least 10 kg); AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has a diagnosis of SBS confirmed by **< 200 cm small intestine length; AND**
4. Member is dependent on parenteral support confirmed by one of the following:
  - a) 18 years of age and older: at least 12 months of dependence, requiring support 3 or more times per week; OR
  - b) 17 years of age and under: at least 3 months of dependence, providing at least 30% of total caloric /fluid needs; AND
5. Chart notes must document the baseline weekly volume of parenteral support; AND
6. Chart notes must document weight; AND
7. Member does not have colorectal cancer.
8. **Dosage allowed/Quantity limit:** 0.05 mg/kg once daily subcutaneously.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must show at least a 20% reduced volume of parenteral support need since treatment initiation.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Gattex (teduglutide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
06/29/2020	New policy for Gattex created.
06/26/2023	Policy transferred to new template; removal of colonoscopy documentation within the past 6 months if 18 years of age and older; removed exclusion of active malignancy in reauthorization criteria; added confirmation of SBS with <200 cm bowel length

#### References:

1. Gattex [package insert]. Lexington, MA: Shire-NPS Pharmaceuticals Inc; 2022.
2. Pironi L, Arends J, Bozzetti F, et al. ESPEN guidelines on chronic intestinal failure in adults. *Clinical Nutrition*. 2016;35(2):247-307. doi:10.1016/j.clnu.2016.01.020
3. 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(6):1473-1481. doi:10.1053/j.gastro.2012.09.007
4. Kocoshis SA, Merritt RJ, Hill S, et al. Safety and Efficacy of Teduglutide in Pediatric Patients With Intestinal Failure due to Short Bowel Syndrome: A 24-Week, Phase III Study. *Journal of Parenteral and Enteral Nutrition*. 2019;44(4):621-631. doi:10.1002/jpen.1690
5. Carter BA, Cohran VC, Cole CR, et al. Outcomes from a 12-Week, Open-Label, Multicenter Clinical Trial of Teduglutide in Pediatric Short Bowel Syndrome. *The Journal of Pediatrics*. 2017;181:102-111. doi:10.1016/j.jpeds.2016.10.027
6. Iyer KR, Kunecki M, Boullata JI, et al. Independence From Parenteral Nutrition and Intravenous Fluid Support During Treatment With Teduglutide Among Patients With Intestinal Failure Associated With Short Bowel Syndrome. *Journal of Parenteral and Enteral Nutrition*. 2016;41(6):946-951. doi:10.1177/01486071166807912021
7. Iyer K, DiBaise JK, Rubio-Tapia A. AGA Clinical Practice Update on Management of Short Bowel Syndrome: Expert Review. *Clin Gastroenterol Hepatol*. 2022;20(10):2185-2194.e2. doi:10.1016/j.cgh.2022.05.032
8. Georgia Code Title 33 – Insurance Chapter 20A - Managed Health Care Plans Article 2 - Patient's Right to Independent Review § 33-20A-31 Definitions. Justia US Law. Accessed April 25, 2023. <https://law.justia.com/codes/georgia/2021/title-33/chapter-20a/article-2/section-33-20a-31/>.

Effective date: 01/01/2024

Revised date: 06/26/2023