

PHARMACY POLICY STATEMENT	
North Carolina Marketplace	
DRUG NAME	Gattex (teduglutide)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see "dosage allowed" below
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Gattex (teduglutide) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

SHORT BOWEL SYNDROME (SBS)

For **initial** authorization:

- 1. Member is 1 year of age or older (must weigh at least 10kg or 22 pounds); AND
- 2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
- 3. Member has a diagnosis of short bowel syndrome and is dependent on parenteral support, defined by one of the following: ^{3,5}
 - a) 18 years of age and over: At least 12 months of dependence, requiring support 3 or more times per week
 - b) 17 years of age and under: At least 3 months of dependence, providing at least 30% of caloric/fluid needs: AND
- 4. Chart notes must document the baseline weekly volume of parenteral support; AND
- 5. Members 18 years old or older must have a colonoscopy within the past 6 months; AND
- 6. Member does not have colorectal cancer.
- 7. **Dosage allowed:** 0.05mg/kg once daily. Weight must be included in chart notes.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For reauthorization:

- 1. Member has not developed an active gastrointestinal malignancy; AND
- 2. Chart notes have been provided that show at least a 20% reduced volume of parenteral support need since treatment initiation.^{3,4}

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Gattex (teduglutide) not medically necessary for the treatment of diseases that are not listed in this document.

Qualified Health Plans offered in North Carolina by CareSource North Carolina Co., d/b/a CareSource.



DATE	ACTION/DESCRIPTION
06/29/2020	New policy for Gattex created.
06/10/2021	Annual review, no changes

References:

- 1. Gattex [package insert]. Lexington, MA: Shire-NPS Pharmaceuticals Inc: 2019.
- 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
- 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:10.1177/0148607116680791

Effective date: 01/01/2023 Revised date: 06/10/2021