

Effective date: 02/01/2022
Review date: 12/2021, 8/2022, 5/2023, 5/2024
Scope: Medicaid

GATTEX (teduglutide)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Gattex is indicated for the treatment of adult and pediatric patients 1 year of age and older with short bowel syndrome (SBS) who are dependent on parenteral support.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. For initial authorization of adult members greater than or equal to 18 years of age: chart notes supporting the use of parenteral nutrition/IV fluids at least 3 times a week for 12 months and current volume of parenteral support in liters per week.
- B. For initial authorization of pediatric member's less than 18 years of age: chart notes supporting the use of parenteral nutrition/IV fluids to account for at least 30% of caloric and/or fluid/electrolyte needs.
- C. For continuation of treatment: chart notes supporting the continued use of parenteral nutrition/IV fluids and current volume of parenteral support in liters per week.
- D. For continuation of treatment for members who were previously on parenteral nutrition and have been weaned off parenteral nutrition/IV fluids while on therapy with the requested drug: chart notes supporting the volume of parenteral support in liters per week required at baseline.

III. CRITERIA FOR INITIAL APPROVAL

Short bowel syndrome (SBS)

Authorization of 6 months may be granted for treatment of SBS when all of the following are met:

- A. Member must be \geq 1 year of age
- B. Member must have a diagnosis of short bowel syndrome (SBS)
- C. Member who has inflammatory bowel disease (IBD) and/or fistulas must be in clinical remission for at least 12 weeks.
- D. Medication is prescribed by or in consultation with a gastroenterologist
- E. Dose does not exceed 0.05mg/kg/day once a day
- F. Member meets one of the following:
 - a. For members greater than or equal to 18 years of age who have been dependent on parenteral nutrition and/or intravenous fluids for at least 12 months and receive intravenous nutrition/fluids at least 3 times a week; OR

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- b. For pediatric members less than 18 years of age who are receiving intravenous nutrition/fluids to account for at least 30% of caloric and/or fluid/electrolyte needs.

IV. CONTINUATION OF THERAPY

Short bowel syndrome (SBS)

- A. Authorization of 6 months may be granted for continued treatment in members requesting reauthorization when the member remains dependent on parenteral nutrition and/or intravenous fluids and whose requirement for parenteral support has decreased by at least 20% from baseline while on therapy with the requested drug.
- B. Authorization of 6 months may be granted for continued treatment in members requesting reauthorization when the member who was previously dependent on parenteral nutrition and/or intravenous fluids has been able to wean off the requirement for parenteral support while on therapy with the requested drug.

V. QUANTITY LIMIT

Gattex 5mg Kit: 1 kit every 30 days (0.04 per day)

VI. REFERENCES

1. Gattex [package insert]. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; 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(6):1473-1481.
3. Schwartz LK, O'Keefe SJD, Fujioka K, et al. Long-term teduglutide for the treatment of patients with intestinal failure associated with short bowel syndrome. *Clin Transl Gastroenterol*. 2016; 7:e142.