

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Gattex under the patient's prescription drug benefit.

Description:

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.

Applicable Drug List:

Non-Formulary: Gattex

Policy/Guideline:

DOCUMENTATION:

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

- A. Initial requests
 - 1. Adult members: Chart notes supporting the use of parenteral nutrition/intravenous (IV) fluids at least 3 times a week for 12 months and current volume of parenteral support in liters per week.
 - 2. Members less than 18 years of age: Chart notes supporting the use of parenteral nutrition/IV fluids accounting for at least 30% of caloric and/or fluid/electrolyte needs.
- B. Continuation requests
 - 1. Members who remain dependent on parenteral nutrition/IV fluids: Chart notes supporting the continued use of parenteral nutrition/IV fluids and current volume of parenteral support in liters per week.
 - 2. Members who were previously dependent on parenteral nutrition/IV fluids and have been weaned off parenteral support while on therapy with the requested drug: Chart notes supporting previous dependence on parenteral nutrition/IV fluids and the volume of parenteral support in liters per week required at baseline.

AETNA BETTER HEALTH® Coverage Policy/Guideline						
Name:	Gattex (teduglutide))	Page:	2 of 3		
Effective Date: 3/14/2025			Last Review Date:	2/2025		
Applies to:	⊠Illinois □New Jersey ⊠Pennsylvania Kids	□Florida ⊠Maryland ⊠Virginia	⊠Florida Kids □Michigan □Texas			

COVERAGE CRITERIA:

Short bowel syndrome (SBS)

- A. Authorization of 6 months may be granted for treatment of short bowel syndrome in adult members who have been dependent on parenteral nutrition and/or intravenous (IV) fluids for at least 12 months and are receiving parenteral nutrition and/or IV fluids at least 3 times a week.
- B. Authorization of 6 months may be granted for treatment of short bowel syndrome in members less than 18 years of age who are receiving parenteral nutrition and/or IV fluids to account for at least 30% of caloric and/or fluid/electrolyte needs.

CONTINUATION OF THERAPY:

Short bowel syndrome (SBS)

- A. Authorization of 6 months may be granted for members who are using the requested medication for SBS and who remain dependent on parenteral nutrition and/or intravenous (IV) 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 members who are using the requested medication for SBS and who were previously dependent on parenteral nutrition and/or IV fluids and have been able to wean off the requirement for parenteral support while on therapy with the requested drug.

Approval Duration and Quantity Restrictions:

Approval: 6 months

Quantity Level Limit:

FDA-recommended Dosing: 0.05 mg/kg/day subcutaneous (SC) once daily. Patients over 75 kg qualify for an exception limit. Renal dose adjustment (eGFR less than 60 mL/min/1.73m2): 0.025 mg/kg once daily.

References:

- 1. Gattex [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2022.
- 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(2):e142.

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4. 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.