

Specialty Guideline Management

Gattex

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Gattex	teduglutide

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 Indications

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.

Documentation

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

Initial requests

- 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.

- 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.

Continuation requests

- 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.
- 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.

Coverage Criteria

Short bowel syndrome (SBS)¹⁻⁴

Authorization of 6 months may be granted for treatment of short bowel syndrome if either of the following criteria are met:

- Adult members 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.
- Members less than 18 years of age 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)¹⁻⁴

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization when either of the following is met:

- The member remains dependent on parenteral nutrition and/or intravenous (IV) fluids and the requirement for parenteral support has decreased by at least 20% from baseline while on therapy with the requested drug.
- The member was 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.

Dosage And Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

References

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