Reference number(s)
1838-A

SPECIALTY GUIDELINE MANAGEMENT

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
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. 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.

III. CRITERIA FOR INITIAL APPROVAL

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.

IV. 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.

V. DOSAGE AND ADMINISTRATION

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

VI. 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.
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.