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
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 for members who remain dependent on parenteral nutrition and/or intravenous fluids: 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)

A. Authorization of 6 months may be granted for treatment of short bowel syndrome in adult 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.
B. Authorization of 6 months may be granted for treatment of short bowel syndrome in 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. 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: Shire-NPS Pharmaceuticals, Inc.; January 2021.
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 Gastroenerol*. 2016; 7:e142.