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 patients with short bowel syndrome (SBS) who are dependent on parenteral support.

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:
A. For initial authorization: chart notes supporting the use of parenteral nutrition/IV fluids for 12 months and current volume of parenteral support in liters per week
B. 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

III. CRITERIA FOR INITIAL APPROVAL

Short bowel syndrome (SBS)
Authorization of 6 months may be granted for treatment of short bowel syndrome in members who have been dependent on parenteral nutrition and/or intravenous fluids for at least 12 months.

IV. CONTINUATION OF THERAPY

Short bowel syndrome (SBS)
Authorization of 6 months may be granted for treatment of short bowel syndrome in members who remain dependent on parenteral nutrition and/or intravenous fluids and whose requirement for parenteral support has decreased by at least 20% from baseline while on Gattex therapy.

V. REFERENCES

1. Gattex [package insert]. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; July 2016.
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.