Teduglutide (Gattex®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO066

Description

Teduglutide (Gattex) is a subcutaneously administered recombinant synthetic glucagon like peptide 2 (GLP-2) analog.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit	DDID
teduglutide (Gattex)	5 mg vial kit (one vial)	Short Bowel Syndrome (SBS)	1 vial/1 day	177513
	5 mg vial kit (30 vial)		30 vials/30 days	

Initial Evaluation

I. Teduglutide (Gattex) may be considered medically necessary when the following criteria below are met:
   A. Member is one year of age or older and weighs more than 10 kg; **AND**
   B. Teduglutide (Gattex) has been prescribed by, or consultation with a specialist in gastroenterology; **AND**
   C. A diagnosis of **Short Bowel Syndrome**; **AND**
      1. Member dependence on parenteral nutrition/intravenous support for at least 12 months; **AND**
      2. Member dependence on parenteral nutrition at least three times a week; **AND**
      3. Laboratory assessment within the last six months of bilirubin, alkaline phosphatase, lipase and amylase to rule out gallbladder, biliary tract or pancreatic disease; **AND**
      4. Colonoscopy within the last 6 months to rule out colorectal polyps or small bowel neoplasia in adult members; **OR**
      5. Fecal occult blood testing in children and adolescents within the last 6 months; **AND**
         i. Documentation of a follow-up colonoscopy for any positive fecal occult blood test

II. Teduglutide (Gattex) is considered investigational when used for all other conditions, including but not limited to:
   A. Crohn's disease
   B. Enterocutaneous Fistula (ECF)
   C. Gastric emptying

Renewal Evaluation

I. Clinical documentation of response to therapy as demonstrated by:
   A. Decrease in volume of parenteral or intravenous nutritional support; **OR**
   B. Decrease in number of days of parenteral or intravenous nutritional support; **AND**
II. Colonoscopy performed within the last 12 months to rule out colorectal polyps or small bowel neoplasia upon first renewal, and, no less than every five years; **AND**
III. Bilirubin, alkaline phosphatase, lipase, and amylase laboratory assessment to rule out gallbladder, biliary tract or pancreatic disease within the last six months.

Supporting Evidence

I. Teduglutide (Gattex) is FDA approved for treatment adults and pediatric patients 1 year of age or older with Short Bowel Syndrome (SBS) who are dependent on parenteral support.
II. The pivotal trial included patients with SBS who were dependent on parenteral nutrition/intravenous support for at least 12 months and at least 3 times per week.
III. There is a lack of strong scientific evidence from randomized controlled trials supporting safety and efficacy for an increased dosing frequency. The higher dose treatment arm did not demonstrate a statistically significant difference when compared to placebo.
IV. Colonoscopies should be completed again 1 year after treatment then no less frequently than every 5 years to evaluate for polyps and gastrointestinal malignancies.
V. Lab assessments are recommended every 6 months to evaluate for gallbladder, biliary tract and pancreatic disease.

Investigational or Not Medically Necessary Uses

I. Crohn's Disease
   A. Phase II clinical trials have evaluated teduglutide for the treatment of Crohn's disease.
   B. Clinical concerns for the safety of teduglutide in patients with Crohn's disease include neoplastic growth, intestinal obstruction and biliary and pancreatic disease.
   C. Large, well-controlled clinical trials are needed to demonstrate benefit of use of teduglutide in patients with Crohn's Disease.
II. Clinical trials are ongoing in the following indications:
   A. Enterocutaneous Fistula (ECF)
   B. Gastric emptying

References

1. Gattex [Prescribing Information]. Bedminister, NJ: NPS Pharmaceutical; June 2019.
2. Jeppesen PB, Gilroy R, Pertkiewicz M, Allard JP, Messing B, O'Keefe SJ. Randomized placebo-controlled trial of teduglutide in reducing parenteral nutrition and/or intravenous fluid requirements in patients with short bowel syndrome. Gut. 2011 Jul;60(7):902-14

Policy Implementation/Update:

Date Created	May 2013
Date Effective	May 2013
Last Updated	August 2013
Last Reviewed	05/2013, 09/2013, 06/2019

Action and Summary of Changes	Date
Created new policy format. Addition of new FDA approved indication in pediatric population.	06/2019