Gattex (teduglutide [rDNA origin])

Override(s)	Approval Duration
Prior Authorization	Initial approval: 7 months Maintenance approval: 1 year

Medications
Gattex (teduglutide [rDNA origin])

APPROVAL CRITERIA

Initial requests for Gattex (teduglutide [rDNA origin]) may be approved if the following criteria are met:

I. Individual is 1 year of age or older; **AND**
II. Documentation is provided that individual has a diagnosis of Short Bowel Syndrome (SBS), defined as having less than 200 cm of functional small intestine remaining as a result of one of the following (AGA 2003):
    A. Acquired through surgical bowel resection; **OR**
    B. Congenital (jejunal or ileal intestinal atresia);

AND

III. Documentation is provided that individual is dependent on parenteral nutrition (PN) support **[submission of recent PN support orders and support orders from at least 3 months prior required]**; **AND**
IV. Documentation is provided that individual requires PN at least 3 times per week (O'Keefe 2013); **AND**
V. Documentation is provided that individual is unable to: (NCT02682381, clinicaltrials.gov)
    A. Reduce PN volume by at least 10% over the previous 3 months; **OR**
    B. Advance oral/enteral feeing support by at least 10% over the previous 3 months.

Continuation requests for Gattex (teduglutide [rDNA origin]) may be approved if the following criteria are met:

I. Individual has met initiation criteria, and one of the following:
    A. Documentation is provided that individual remains dependent on PN support, but has achieved at least a 20% volume reduction in weekly parenteral support and maintained that reduction for four (4) or more weeks without weight loss compared to baseline while on Gattex **[submission of PN support orders from time of Gattex initiation AND most recent support orders required]**; **OR**
    B. Documentation is provided that individual was previously dependent on PN support, but has successfully weaned off while on Gattex **[submission of last PN support orders while on Gattex required]**.

Requests for Gattex (teduglutide [rDNA origin]) may not be approved for the following:

I. Individual has a diagnosis of an active gastrointestinal-associated (GI tract, hepatobiliary, pancreatic, colorectal, small bowel) malignancy; **OR**

II. Individual has a diagnosis of intestinal or stomal obstruction; **OR**
III. Individual has severe hepatic impairment (Child-Pugh Class C).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 7, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. American Gastroenterological Association Medical Position Statement: Short bowel syndrome and intestinal transplantation. *Gastroenterology*. 2003; 124(4):1105-1110. Available from: https://www.gastrojournal.org/article/S0016-5085(03)00052-0/fulltext.
6. Pironi L, Arends J, Bozzetti F, et al. ESPEN guidelines on chronic intestinal failure in adults. Clin Nutr. 2016;35(2):247-307. Available at: www.espen.org/files/ESPEN-Guidelines/1__ESPEN_guidelines_on_chronic_intestinal_failure_in_adults.pdf.
7. Short Bowel Syndrome Research Study for Children Up To 17 Years of Age on Parenteral Nutrition. ClinicalTrials.gov Identifier: NCT02682381. Official Title: A 24-Week Double-blind, Safety, Efficacy, and Pharmacodynamic Study Investigating Two Doses of Teduglutide in Pediatric Subjects Through 17 Years of Age With Short Bowel Syndrome Who Are Dependent on Parenteral Support. Available at: https://clinicaltrials.gov/ct2/show/results/NCT02682381?term=NCT02682381&rank=1.
8. Schwartz LK, O'Keefe JD, Fujioka K, et.al. Long-term teduglutide for the treatment of patients with intestinal failure associated with short bowel syndrome. Clin Trans Gastroenterology. 2016;7, e142; doi:10.1038/ctg.2015.69.
9. O'Keefe SJ, Jeppesen, PB, Gilroy R, et.al. Safety and efficacy of teduglutide after 52 weeks of treatment in patients with short bowel intestinal failure. *Clin Gastro Heaptology.* 2013; 11:815-823. Available from: https://www.cghjournal.org/article/S1542-3565(13)00087-6/pdf.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.