Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

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 has been on stable parenteral nutrition/intravenous (PN/IV) support, defined as the inability to significantly reduce PN/IV support, for at least 3 months (NCT02682381, clinicaltrials.gov); **AND**
IV. Documentation is provided that individual requires PN at least 3 times per week.

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

I. Documentation is provided that individual has achieved at least a 20% reduction in weekly parenteral support and maintained that reduction for four (4) or more weeks compared to baseline.

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).

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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: August 30, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; 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. Accessed on: August 30, 2019.
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. Accessed on: August 30, 2019.
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 Accessed on October 13, 2020.
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. Accessed October 15, 2020.

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.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.