

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Gattex (teduglutide [rDNA origin])

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Gattex (teduglutide [rDNA origin])

APPROVAL CRITERIA

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. 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. Individual has been dependent on parenteral nutrition/intravenous (PN/IV) support for at least 3 months (NCT02682381, clinicaltrials.gov); **AND**
- IV. Individual requires PN at least 3 times per week.

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).

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

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.

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Applicable	X	X	X	X	X	X	NA

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](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](https://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 September 9, 2019.