Clinical Policy Title:	teduglutide
Policy Number:	RxA.150
Drug(s) Applied:	Gattex®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All line of business

Background

Teduglutide is a glucagon-like peptide-2 (GLP-2) analog indicated for treatment of adult and pediatric patients 1 year of age and older with short bowel syndrome (SBS) who are dependent on parenteral support.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
teduglutide (Gattex®)	Short Bowel Syndrome	0.05 mg/kg SC once daily	0.05 mg/kg/day

Dosage Forms

- Single-dose vial: 5 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administer by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Short Bowel Syndrome (must meet all):

1. Member has a diagnosis of SBS;
2. Prescribed by or in consultation with a gastroenterologist or a provider who specializes in SBS;
3. Member is one (1) year of age or older;
4. Member is dependent on parenteral nutrition and/or other intravenous (IV) fluids for 12 months or greater despite aggressive use of conventional measures and (a or b):
   a. For members 18 years of age or older: Use of parenteral nutrition/IV fluids occurs at least three (3) times a week; or
   b. For members under 18 years of age: Use of parenteral nutrition/IV fluids account for at least 30% of caloric and/or fluid/electrolyte needs;
5. Failure of a 4-week trial of somatropin (e.g., Zorbtive®) unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is (or may be) required for somatropin.*
6. Dose does not exceed 0.05 mg/kg per day;

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Short Bowel Syndrome (must meet all)**:**

1. Member is currently receiving teduglutide that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Requirement for parenteral nutrition or other intravenous support has decreased by at least 20% from baseline since initiation of teduglutide therapy;
3. If request is for a dose increase, new dose does not exceed 0.05 mg/kg per day;

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
GLP-2: Glucagon-Like Peptide-2
IM: Intramuscular/intramuscularly
IV: Intravenous/intravenously
SBS: Short Bowel Syndrome
SC: Subcutaneous/subcutaneously

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
somatropin (e.g., Zorbtive®)	0.1 mg/kg SC once daily to a maximum daily dose of 8 mg for 4 weeks. Refer to prescribing information for information on dosage titration and fluid management.	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None
- Boxed Warning(s):
  - None

APPENDIX D: General Information

- Intestinal obstruction: In patients who develop intestinal or stomal obstruction, temporarily discontinue teduglutide pending further clinical evaluation and management.
- Fluid overload, including congestive heart failure: If fluid overload occurs, adjust parenteral support and

reassess continued teduglutide treatment.

- Biliary and pancreatic disease: Obtain bilirubin, alkaline phosphatase, lipase, and amylase every 6 months. If clinically meaningful changes are seen, further evaluation is recommended including imaging and reassess continued teduglutide treatment.
- Teduglutide is not for IV or IM administration.

References

1. Gattex Prescribing Information. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; January 2021. Available at http://www.gattex.com. Accessed March 3, 2021.
2. Parrish CR, DiBaise JK. Managing the adult patient with short bowel syndrome. Gastroenterology & Hepatology. October 2017; 13(10): 600-608.
3. Seidner DL, Schwartz LK, Winkler MF, et al. Increased intestinal absorption in the era of teduglutide and its impact on management strategies in patients with short bowel syndrome – associated intestinal failure. JPEN. 2013; 37: 201-2011.
4. 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.
5. 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 Gastroenterol Hepatol. Jul 2013; 11 (7): 815-823.
6. 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.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy description table was updated. 2. Dosage form was updated. 3. Continuation therapy criteria II.A.1. was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance". 4. Initial therapy and continued therapy approval duration for "commercial" was updated. 5. Contraindications and boxed warning was rephrased to "none". 6. References were updated.	06/15/2020	09/14/2020
Policy was reviewed: 1. Clinical Policy title was updated. 2. Initial criteria for approval and duration updated. 3. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..." 4. Appendix D was added. 5. References were reviewed and updated.	03/03/2021	06/10/2021