Clinical Policy: Teduglutide (Gattex)

Reference Number: PA.CP.PHAR.114
Effective Date: 01/2018
Last Review Date: 01/2023

Coding Implications
Revision Log

Description
Teduglutide (Gattex®) is a glucagon-like peptide-2 analog.

FDA Approved Indication(s)
Gattex is 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.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness that Gattex is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Short Bowel Syndrome (must meet all):

1. Diagnosis of short bowel syndrome;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 1 year;
4. Weight ≥ 10 kg;
5. Dependent on parenteral nutrition or other intravenous support for ≥ 12 months;
6. Dose does not exceed 0.05 mg/kg per day.

Approval duration: 12 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Requirement for parenteral nutrition or other intravenous support has decreased since initiation of Gattex therapy;
3. If request is for a dose increase, new dose does not exceed 0.05 mg/kg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
SBS: short bowel syndrome

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
SBS	0.05 mg/kg SC QD	0.05 mg/kg/day

V. Product Availability

Single-use vial: 5 mg

VI. References

1. Gattex Prescribing Information. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; October 2022. Available at http://www.gattex.com. Accessed November 16, 2022.
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. Iyer K, DiBiase JK, and Rubio-Tapia A. AGA clinical practice update on management of short bowel sydrnome: expert review. *Gastroenterology & Hepatology* 2022;20:2185-2194.
5. Wales PW, Nasr A, de Silva N, Yamada J. Human growth hormone and glutamine for patients with short bowel syndrome. Cochrane Database of Systematic Reviews 2010, Issue 6. Art. No.: CD006321.

Reviews, Revisions, and Approvals	Date	Approval Date
Age added. Preferencing for Zorptive added. The following criteria are removed given the 12-month PN requirement: colonosopy; PN ≥ 3 times per week; use of antimotility and antisecretory agents. "Consecutive" removed from the 12-month PN requirement. Initial duration is increased from 6 to 12 months to allow more time for therapeutic response; continued therapy duration is increased from 6 to 12 months. References reviewed and updated.	02/2018	
1Q 2019 annual review; references reviewed and updated.	01/2019	

Reviews, Revisions, and Approvals	Date	Approval Date
1Q 2020 annual review: revised age requirement from 18 years to 1 year to align with updated prescribing information; references reviewed and updated.	01/2020	
1Q 2021 annual review: references reviewed and updated.	01/2021	
1Q 2022 annual review: added minimum weight requirement based on prescribing information; references reviewed and updated.	01/2022	
1Q 2023 annual review: no significant changes; references reviewed and updated.	01/2023	