Clinical Policy: Teduglutide (Gattex)

Reference Number: PA.CP.PHAR.114
Effective Date: 01/2018
Last Review Date: 01/2025

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;
6. Documentation of member's current body weight (in kg);
7. 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.PHARM.01) applies;
2. Requirement for parenteral nutrition or other intravenous support has decreased since initiation of Gattex therapy;
3. Documentation of member's current body weight (in kg);
4. 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.PHARM.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: Takeda Pharmaceuticals, Inc.; September 2024. Available at http://www.gattex.com. Accessed October 18, 2024.
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.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3490	Unclassified drugs

Reviews, Revisions, and Approvals	Date
Age added. Preferencing for Zorptive added. The following criteria are removed given the 12-month PN requirement: colonosopy; PN ≥ 3 times	02/2018

Reviews, Revisions, and Approvals	Date
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.	
1Q 2019 annual review; references reviewed and updated.	01/2019
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
1Q 2024 annual review: added criteria, "documentation requirement of current body weight in kg"; references reviewed and updated.	01/2024
1Q 2025 annual review: no significant changes; references reviewed and updated.	01/2025