Clinical Policy: Teduglutide (Gattex)

Reference Number: PA.CP.PHAR.114
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for teduglutide (Gattex®)

FDA Approved Indication(s)
Gattex is indicated for treatment of adult patients with short bowel syndrome 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.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and 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 ≥ 18 years;
4. Dependent on parenteral nutrition or other intravenous support for ≥ 12 months;
5. Dose does not exceed 0.05 mg/kg/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 Pennsylvania Health and 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 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/day.

Approval duration: 12 months

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

1. Currently receiving medication via Pennsylvania Health and 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

Background

Description/Mechanism of Action:
The active ingredient, teduglutide (rDNA origin), is a 33 amino acid glucagon-like peptide-2 (GLP-2) analog manufactured using a strain of Escherichia coli modified by recombinant DNA technology. Teduglutide is an analog of naturally occurring human GLP-2, a peptide secreted by L-cells of the distal intestine. GLP-2 is known to increase intestinal and portal blood flow, and inhibit gastric acid secretion. Teduglutide binds to the GLP-2 receptors located in intestinal subpopulations of enteroendocrine cells, subepithelial myofibroblasts and enteric neurons of the submucosal and myenteric plexus. Activation of these receptors results in the local release of multiple mediators including insulin-like growth factor (IGF)-1, nitric oxide and keratinocyte growth factor (KGF).

Formulations:
Single-use vial: 5 mg teduglutide as a lyophilized powder that upon reconstitution with the 0.5 mL Sterile Water for Injection provided in the prefilled syringe delivers a maximum of 0.38 mL of the reconstituted sterile solution which contains 3.8 mg of teduglutide.

Appendices

Appendix A: Abbreviation Key

GI: gastrointestinal
GLP-2: glucoagon-like peptide-2
IGF: insulin-like growth factor
KGF: keratinocyte growth factor
SBS: short bowel syndrome

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
N/A	

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	02/18	

Reviews, Revisions, and Approvals	Date	Approval Date
duration is increased from 6 to 12 months. References reviewed and updated.		

References

1. Gattex Prescribing Information. McPherson, KS: Hospira, Inc.; July 2016. Available at http://www.gattex.com. Accessed November 2017.
2. 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.
3. American Gastroenterological Association. American Gastroenterological Association medical position statement: short bowel syndrome and intestinal transplantation. Gastroenterology. 2003 Apr;124(4):1105-10.