Clinical Policy: Teduglutide (Gattex)

Reference Number: CP.PHAR.114
Effective Date: 05/13
Last Review Date: 04/17

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that Gattex is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Short Bowel Syndrome (must meet all):

1. Prescribed by or in consultation with a gastroenterologist;
2. Diagnosis of short bowel syndrome;
3. Completed colonoscopy (or alternate imaging) with removal of any polyps within the last 6 months;
4. Dependent on parenteral support (parenteral nutrition/intravenous support) for ≥ 12 consecutive months;
5. Currently requires parenteral nutrition ≥ 3 times per week despite optimized dietary modifications and use of the following medications (a and b):
   a. An antimotility agent (e.g. loperamide, diphenoxylate with atropine, opioids);
   b. An antisecretory agent (e.g. histamine-2 receptor blockers, proton pump inhibitors, octreotide);
6. Prescribed dose does not exceed 0.05 mg/kg body weight/day administered subcutaneously.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

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

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Requirement for parenteral support has decreased since initiation of Gattex therapy;
3. Completed follow-up colonoscopy (or alternate imaging) with removal of any polyps if Gattex has been prescribed for ≥ 1 year. If no polyps found at 1 year follow-up colonoscopy, further colonoscopies needed no less frequently than every 5 years.

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

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.

FDA Approved Indication:

Gattex (teduglutide) is a GLP-2 analog /reconstituted subcutaneous injectable formulation indicated for:

- Treatment of adult patients with short bowel syndrome (SBS) who are dependent on parenteral support.

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
Policy developed	05/13	05/13
Added clinical information to background and safety precautions Removed requirement for failure of Zorbtive from criteria	04/14	05/14
Added safety information benzodiazepines	01/15	04/15
Policy converted to new template. Criteria: added age per PI; added specialist; added colonoscopy requirement per PI; PI clinical trials support history of PS for 12 consecutive months; added current 3 x per week PN requirement per PI clinical trials; added use of antimotility and antisecretory medications; added max dose per PI PS reduction requirement on re-authorization; added malignancy and obstruction contraindications per PI; added concurrent use of growth hormone exclusion..	03/16	04/16
Removed safety criteria that are not absolute contraindications or related to black box warnings. Removed age restriction. Removed contraindications in continued approval section.	03/17	04/17

References

1. Gattex Prescribing Information. McPherson, KS: Hospira, Inc.; June 2014. Available at http://www.gattex.com. Accessed February 18, 2016.
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.

Important Reminder

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.