Clinical Policy: Teduglutide (Gattex)
Reference Number: CP.PHAR.114
Effective Date: 05/13
Last Review Date: 04/17

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 \(\geq 12\) consecutive months;
      5. Currently requires parenteral nutrition \(\geq 3\) 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 \(\geq 1\) 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.

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<thead>
<tr>
<th>HCPCS Codes</th>
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CLINICAL POLICY
Teduglutide

Reviews, Revisions, and Approvals

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

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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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.

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**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](http://www.cms.gov) for additional information.

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