

Clinical Policy: Teduglutide (Gattex)

Reference Number: CP. PHAR.114

Effective Date: 05.01.13

Last Review Date: 02.19

Line of Business: Commercial, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

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

FDA Approved Indication(s)

Gattex is indicated for treatment of adult patients with short bowel syndrome (SBS) who are dependent on parenteral support.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval 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. Diagnosis of SBS;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age \geq 18 years;
4. Dependent on parenteral nutrition or other intravenous support for \geq 12 months;
5. Failure of a 4-week trial of somatropin (e.g., Zorbtive[®], Norditropin[®], Humatrope[®]), unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization is (or may be) required for somatropin*
6. Dose does not exceed 0.05 mg/kg per day.

Approval duration:

Medicaid - 12 months

Commercial – 12 months or to member’s renewal period, whichever is longer

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

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 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:

Medicaid - 12 months

Commercial - 12 months or to member’s renewal period, whichever is longer

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

SBS: short bowel syndrome

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
somatropin (e.g., Zorbtive, Norditropin, Humatrope)	Zorbtive: 0.1 mg/kg SC QD Refer to prescribing information (<i>Somatropin, rh-GH doses must be individualized and are highly variable depending on the nature and severity of the disease, the formulation being used, and on patient response</i>)	Zorbtive: 8 mg/day for 4 weeks

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

None reported

V. Dosage and Administration

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

VI. Product Availability

Single-use vial: 5 mg

VII. References

- Gattex Prescribing Information. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; July 2016. Available at <http://www.gattex.com>. Accessed November 8, 2018.
- Parrish CR, DiBaise JK. Managing the adult patient with short bowel syndrome. *Gastroenterology & Hepatology*. October 2017; 13(10): 600-608.
- 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added clinical information to background and safety precautions Removed requirement for failure of Zorbtive from criteria	04.01.14	05.14
Added safety information benzodiazepines	01.01.15	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..	03.01.16	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.	03.01.17	04.17
1Q18 annual review: Policies combined for Medicaid and Commercial lines of business; age added; preferencing for Zorptive added; the following criteria are removed given the 12-month PN requirement: colonoscopy; 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.	12.01.17	02.18
3Q 2018 annual review: broadened redirection to any somatropin product, listing preferred products as examples; references reviewed and updated.	05.09.18	08.18
1Q 2019 annual review; no significant changes; references reviewed and updated.	11.13.18	02.19

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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.

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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.

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