Clinical Policy: Teduglutide (Gattex)

Reference Number: ERX.SPA.301
Effective Date: 03.01.19
Last Review Date: 02.22
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 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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 ≥ 1 year;
4. Weight ≥ 10 kg;
5. Dependent on parenteral nutrition or other intravenous support for ≥ 12 months;
6. If age ≥ 18 years, failure of a 4-week trial of somatropin (*Norditropin® is preferred*), unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for somatropin*
7. Dose does not exceed 0.05 mg/kg per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions 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: 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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., Norditropin)	Refer to prescribing information (*dosing is individualized depending on nature and severity of disease, formulation, and patient response*)	Varies

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

1. Gattex Prescribing Information. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; January 2021. Available at http://www.gattex.com. Accessed November 11, 2021.
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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	11.13.18	02.19
No significant changes; revised age requirement from 18 years to 1 year to align with updated prescribing information; references reviewed and updated.	06.07.19	
1Q 2020 annual review: somatropin trial limited to adults - Norditropin is designated as a preferred drug; references reviewed and updated.	11.19.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	10.22.20	02.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2022 annual review: added minimum weight requirement based on prescribing information; references reviewed and updated.	11.11.21	02.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.