



Drug Coverage Policy

Effective Date..... 10/1/2024

Coverage Policy Number IP0288

Policy Title.....Gattex

Gastroenterology – Gattex

- Gattex® (teduglutide subcutaneous injection – Shire)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

OVERVIEW

Gattex, a glucagon-like peptide-2 (GLP-2) analog, is indicated for the treatment of **short bowel syndrome** in patients \geq 1 year of age who are dependent on parenteral support.¹

Clinical Efficacy

In a study involving adults (n = 86) with short bowel syndrome requiring parenteral support at least 3 days per week, more patients treated with Gattex through Month 6 achieved \geq 20%

reduction in weekly intravenous volume (63% vs. 30% with placebo).¹ The mean reduction in intravenous volume was 4.4 liters with Gattex vs. 2.3 liters with placebo. When treated over an additional 2 years, the mean reduction from baseline was 7.55 liters. Ten patients were weaned off of nutritional support and remained on Gattex therapy. At Week 24 of a pediatric study, 69% of patients (n = 18/26) reduced parenteral support volume by at least 20% with Gattex. The mean reduction in intravenous volume was -23 mL/kg/day, a 42% reduction in parenteral support. Three patients were weaned off of parenteral nutritional support.

Safety

Gattex has Warnings and Precautions regarding acceleration of neoplastic growth, colorectal polyps, intestinal obstruction, biliary and pancreatic disease, fluid overload (including congestive heart failure), and potential for increased absorption of concomitant oral medications, particularly those with a narrow therapeutic index.¹ It was approved with a Risk Evaluation and Mitigation Strategy (REMS) program intended to inform healthcare providers and patients about serious risks, including the risks of possible acceleration of neoplastic growth and enhancement of colon polyp growth, gastrointestinal obstruction, and biliary and pancreatic disorders.²

Medical Necessity Criteria

Gattex is considered medically necessary when the following criteria are met:

FDA-Approved Indication

- 1. Short Bowel Syndrome.** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - A) Initial Therapy.** Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
 - i.** Patient is \geq 1 year of age; AND
 - ii.** Patient meets ONE of the following (a or b):
 - a)** Patient is currently receiving parenteral nutrition on 3 or more days per week; OR
 - b)** According to the prescriber, the patient is unable to receive adequate total parenteral nutrition (TPN) required for caloric needs; AND
 - iii.** The medication is prescribed by or in consultation with a gastroenterologist.
 - B) Patient is Currently Receiving Gattex.** Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
 - i.** Patient has already received at least 6 months of therapy with Gattex; AND
Note: A patient who has received < 6 months of continuous therapy should be considered under criterion 1A (Initial Therapy).
 - ii.** According to the prescriber, the patient has experienced at least a 20% decrease from baseline in the weekly volume of parenteral nutrition; AND
 - iii.** The medication is prescribed by or in consultation with a gastroenterologist.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Gattex® subcutaneous injection [prescribing information]. Lexington, MA: Shire; February 2024.
2. Gattex REMS; Shire Web site. Available at: <http://www.gattexrems.com/>. Accessed on June 24, 2024.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	<p>Updated coverage policy title from “Teduglutide” to “Gastroenterology – Gattex.”</p> <p>Short Bowel Syndrome. Initial Therapy: Added criteria to establish, “According to the prescriber, the patient is unable to receive adequate total parenteral nutrition (TPN) required for caloric needs.”</p> <p>Currently Receiving Gattex: Added criteria to establish, “Patient has already received at least 6 months of therapy with Gattex; Note: A patient who has received < 6 months of continuous therapy should be considered under criterion 1A (Initial Therapy)”.</p>	10/01/2024

The policy effective date is in force until updated or retired.

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