

Cigna National Preferred Formulary Coverage Policy



Effective Date 1/1/2021

Next Review Date... 1/1/2022

Coverage Policy Number NPF375

Prior Authorization

Gastroenterology - Gattex (teduglutide injection for subcutaneous use)

Table of Contents

NPF Coverage Policy	1
Background.....	2
References	2
Last Revision Details	2

Related Coverage Resources

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. 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.

NPF Coverage Policy

Cigna covers teduglutide products (Gattex) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

Prior authorization is recommended for prescription benefit coverage of Gattex. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of individuals treated with Gattex as well as the monitoring required for adverse events and long-term efficacy, approval requires Gattex to be prescribed by or in consultation with a physician who specializes in the condition being treated.

FDA Indication(s)

1. **Short Bowel Syndrome.** Approve for the duration noted if the individual meets the following criteria (A or B):
 - A) **Initial Therapy.** Approve for 6 months if the individual meets ALL of the following (i, ii, and iii):
 - i. Individual is ≥ 1 year of age; AND
 - ii. Individual meets ONE of the following (a or b):

- a) Individual is currently receiving parenteral nutrition on 3 or more days per week; OR
 - b) According to the prescriber, the individual 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) Individual is Currently Receiving Gattex.** Approve for 1 year if the individual meets all of the following (i, ii, and iii):
- i. Individual has already received at least 6 months of therapy with Gattex; AND
Note: An individuals who has received < 6 months of continuous therapy should be considered under criterion 1A (Initial Therapy).
 - ii. According to the prescriber, the individual has experienced at least a 20% decrease from baseline in the weekly volume of parenteral nutrition; AND
 - iii. The agent is prescribed by or in consultation with a gastroenterologist.

Conditions Not Covered

Teduglutide (Gattex) is considered experimental, investigational or unproven for ANY other use.

Background

Overview

Gattex is a glucagon-like peptide-2 (GLP-2) analog indicated for the treatment of short bowel syndrome in individuals ≥ 1 year of age who are dependent on parenteral support.¹ In clinical studies, Gattex decreased the volume of parenteral support needed for some individuals with short bowel syndrome and intestinal failure. It is administered via a daily subcutaneous injection.

Clinical Efficacy

In a study involving adults ($n = 86$) with short bowel syndrome requiring parenteral support at least 3 days per week, more individuals 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 individuals were weaned off of nutritional support and remained on Gattex therapy. At Week 24 of a pediatric study, 69% of individuals ($n = 18/26$) 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 individuals were weaned off of parenteral nutritional support.

Safety

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

References

1. Gattex® for injection, for subcutaneous use [prescribing information]. Lexington, MA: Shire/NPS Pharmaceuticals; May 2019.
2. Gattex REMS; Shire Web site. Available at: <http://www.gattexrems.com/>. Accessed on June 17, 2020

Last Revision Details

Annual revision	No changes to the criteria.	06/24/2020
-----------------	-----------------------------	------------

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Cigna Behavioral Health, Inc., Cigna Health Management, Inc., QualCare, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2021 Cigna.