Effective Date **1/15/2024**
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Coverage Policy Number **IP0288**

Teduglutide

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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.

Overview

This policy supports medical necessity review for teduglutide (Gattex®).

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

Medical Necessity Criteria

Teduglutide (Gattex) is considered medically necessary when the following are met:

Short Bowel Syndrome. Individual meets **ALL** of the following criteria:
1. Age 1 year of age or older
2. Currently dependent on parenteral nutrition support
3. 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.

Reauthorization Criteria

Continuation of teduglutide (Gattex) is considered medically necessary for short bowel syndrome when the above medical necessity criteria are met AND there is documentation of beneficial response including the following:

1. According to the prescriber, the individual has experienced at least a 20% decrease from baseline in the weekly volume of parenteral nutrition.

Authorization Duration

Initial approval duration is up to 6 months.
Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW
Gattex, a glucagon-like peptide-2 (GLP-2) analog, is indicated for the treatment of **short bowel syndrome** in patients ≥ 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 ≥ 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]

References

1. Gattex® subcutaneous injection [prescribing information]. Lexington, MA: Shire; October 2022.
2. Gattex REMS; Shire Web site. Available at: http://www.gattexrems.com/. Accessed on June 26, 2023.