PRIOR AUTHORIZATION POLICY

POLICY: Gastroenterology – Gattex Prior Authorization Policy
- Gattex® (teduglutide subcutaneous injection – Takeda)

REVIEW DATE: 06/11/2025

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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 NATIONAL FORMULARY COVERAGE:

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 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 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] Gattex 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]

POLICY STATEMENT

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 patients 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.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 ≥ 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; OR
   - **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.

CONDITIONS NOT COVERED

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is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Gattex® subcutaneous injection [prescribing information]. Cambridge, MA: Takeda; September 2024.
2. Gattex REMS; Shire Web site. Available at: http://www.gattexrems.com/. Accessed on May 30, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	06/28/2023
Annual Revision	No criteria changes.	06/26/2024
Annual Revision	No criteria changes.	06/11/2025