PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/26/2024

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]

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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Gattex is recommended in those who meet the following criteria:

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.
   - **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 patients 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 RECOMMENDED FOR APPROVAL

Coverage of Gattex is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. 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.