MEDICAL MUTUAL®

Drug Policy

Policy:	Gattex (teduglutide)	Annual Review Date: 06/20/2024 Last Revised Date: 06/20/2024

OVERVIEW

Gattex is a glucagon-like peptide-2 (GLP-2) analog indicated for treatment of short bowel syndrome in adults and children who are at least one year of age who are dependent on parenteral support. In clinical studies, Gattex decreased the volume of parenteral support needed for some patients with short bowel syndrome and intestinal failure. It is administered via a daily subcutaneous injection. Patients who take Gattex should be monitored according to the recommendations for imaging (colonoscopy or alternate imaging of the entire colon with removal of polyps) and laboratory assessments (bilirubin, alkaline phosphatase, lipase, and amylase levels). 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 medication. 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 (GI) obstruction, and biliary and pancreatic disorders.

POLICY STATEMENT

This policy involves the use of Gattex. Prior authorization is recommended for pharmacy benefit coverage of Gattex. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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, initial approval requires Gattex be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Short Bowel Syndrome, Initial Therapy**
   Criteria. *Patient must meet the following criteria (A, B, C, D, E and F):*
   A. The patient is ≥ 1 year of age; AND
   B. The patient weighs at least 10 kg; AND

C. The patient is dependent on parenteral support, requiring parenteral nutrition 3 or more days per week; AND
D. Bilirubin, alkaline phosphatase, lipase, and amylase lab values have been assessed within the past 6 months; AND
E. The medication is prescribed by or in consultation with a gastroenterologist; AND
F. The prescriber has completed all REMS program requirements.

2. <u>Short Bowel Syndrome, Patient is Currently Receiving Gattex</u>
Criteria. *Patient must meet the following criteria (A, B, C, D and E):*

A. The patient has already received at least 6 months of therapy with Gattex (Note: Patients who have received < 6 months of continuous therapy should be considered under initial therapy criterion); AND
B. According to the prescriber, the patient has experienced at least a 20% decrease from baseline in the weekly volume of parenteral nutrition; AND
C. The agent is prescribed by or in consultation with a gastroenterologist; AND
D. Bilirubin, alkaline phosphatase, lipase, and amylase lab values have been assessed within the past 6 months; AND
E. The patient has no contraindications to Gattex.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 180 days
B) *Extended Approval:* 365 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Gattex has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Gattex® for injection, for subcutaneous use [prescribing information]. Lexington, MA: Shire/NPS Pharmaceuticals; December 2018.
2. Buchman AL. The medical and surgical management of short bowel syndrome. *MedGenMed*. 2004;6(2):12.
3. Short bowel syndrome. National Digestive Diseases Information Clearinghouse, National Institute of Diabetes and Digestive Kidney Diseases (NIDDKD), National Institutes of Health. Accessed on June 13, 2019. Available at: http://digestive.niddk.nih.gov/ddiseases/pubs/shortbowel/index.aspx.
4. Gattex REMS; Shire Web site. Accessed on June 13, 2019. Available at: http://www.gattexrems.com/.
5. Teduglutide. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 07 June 2019. Accessed on 14 June 2019.