Pharmacy Medical Necessity Guidelines: Gattex® (teduglutide)

Effective: April 11, 2017 (all plans except Tufts Health RITogether)
Effective: June 1, 2017 (Tufts Health RITogether)

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<th>Type of Review – Care Management</th>
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Pharmacy (RX) or Medical (MED) Benefit
RXUM: Department to Review
RXUM: 617.673.0988

This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

**Fax Numbers:**
RXUM: 617.673.0988

**Note:** For Tufts Health Plan Medicare Preferred Members, refer to the Tufts Health Plan Medicare Preferred prior authorization criteria. Background, applicable product and disclaimer information can be found on the last page.

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Gattex (teduglutide [rDNA origin]) for injection is a glucagon-like peptide-2 (GLP-2) analog indicated for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

SBS occurs when a patient has less than 200 cm of functional small intestine, usually as a result of surgical resection of the intestines due to mesenteric thrombosis or embolism, Crohn’s disease, trauma, midgut volvulus, or tumors. Functional SBS may occur in the presence of intact intestine when severe malabsorption occurs. Functional SBS may be associated with chronic intestinal pseudo-obstruction syndrome, celiac disease, radiation enteritis, or congenital villus atrophy. Intestinal failure resulting from SBS occurs when there is not enough intestinal capacity for a patient to absorb sufficient fluids, electrolytes or energy from food on a normal diet, and specialized nutritional therapy becomes necessary. It is believed that approximately two individuals per million have SBS with intestinal failure requiring parenteral support to supplement oral intake.

Up to half of patients with SBS initially require parenteral nutrition and/or fluid support but are able to be weaned from parenteral therapy within two years as their bodies adapt to SBS through mechanisms such as intestinal villous hypertrophy and hyperphagia, in which patients consume up to three times the normal caloric intake. Several gut hormones including enteroglucagon, GLP-2, epidermal growth factor, growth hormone, cholecystokinin, gastrin, insulin, and neurotensin aid in intestinal adaptation to SBS.

Complications of SBS include chronic diarrhea, which may lead to perianal skin breakdown; gastric hypersecretion; nephrolithiasis; vitamin and mineral imbalance, which often leads to osteoporosis; end-stage liver disease from parenteral nutrition; biliary disease necessitating cholecystectomy; and problems associated with central lines, such as catheter infection and catheter thrombosis.

Gattex (teduglutide) is subject to a REMS program consisting of a communication plan and elements to assure safe use. The communication plan includes Dear Healthcare Professional and Dear Professional Society letters to inform prescribers about the risks of possible acceleration of neoplastic growth and enhancement of colon polyp growth, gastrointestinal obstruction, and biliary and pancreatic disorders associated with Gattex (teduglutide). The elements to assure safe use include training that is to be made available to prescribers regarding the risks of Gattex (teduglutide) and recommendations for monitoring patients. In addition, Gattex (teduglutide) has a medication guide educating patients about the warnings and precautions for the medication as well as monitoring parameters.
Besides Gattex (teduglutide), other agents indicated for the treatment of SBS are Zorbtive (somatropin) and NutreStore (L-glutamine). Guidelines for the management of SBS were last updated by the American Gastroenterological Association (AGA) in 2003. The guidelines recommend against peptide-based diets and lactose restriction, while it is recommended to supplement the diet with soluble fiber, fat-soluble vitamins, and the trace elements zinc and selenium. Proton pump inhibitors are recommended, especially during the post-surgical period, to reduce gastric hypersecretion resulting in fluid losses. High doses of loperamide or diphenoxylate/atropine are also recommended to reduce fluid losses. A diet low in oxalate is recommended to prevent nephrolithiasis. Intestinal transplantation is a therapeutic option for patients who do not thrive with parenteral nutrition, including those with impending or overt liver failure, frequent central line infections, and frequent severe dehydration. As of 2003, the AGA guidelines did not recommend the use of glutamine or growth hormone for the management of SBS because they do not lead to morphological changes in the intestine but may cause significant peripheral edema. GLP-2 analogs were purely investigational at the writing of the guidelines.

**COVERAGE GUIDELINES**

The plan may authorize coverage of Gattex (teduglutide) Injection for Members when **ALL** of the following criteria are met:

1. The Member has a documented diagnosis of Short Bowel Syndrome (SBS)
2. The Member has a history of dependence on parenteral nutrition (PN) and/or intravenous (IV) fluids of at least 12 consecutive months continuously
3. The Member will be requiring concurrent parenteral support
4. The Member is 18 years of age or older.

**LIMITATIONS**

1. Initial approval will be limited to six months. A new prior authorization may be submitted at that time for continuation of therapy. Subsequent authorization requests may be given in 12-month intervals based on the submission of medical records documenting tolerance and effectiveness of therapy.
2. The plan does not cover Gattex (teduglutide) for any conditions not listed in the coverage guidelines above unless there is sufficient documentation of efficacy and safety in the published literature.
3. Coverage for Gattex (teduglutide) will be limited as follows:
   - 30 vials per 30 days.

**CODES**

Medical billing codes may not be used for these medications. These medications must be obtained via the Member’s pharmacy benefit.

**REFERENCES**


**APPROVAL HISTORY**

May 14, 2013: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- May 13, 2014: No changes
- May 12, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- April 12, 2016: No changes

**BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. For Tufts Health Plan Medicare Preferred, refer to Tufts Health Plan Medicare Preferred prior authorization criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.