BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

GATTEX® (teduglutide [rDNA origin]) subcutaneous injection Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

- **Criteria for initial therapy:** Gattex (teduglutide) and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Gastroenterologist

  2. Individual is 1 years of age or older weighing at least 10 Kg

  3. Individual has a confirmed diagnosis of short bowel syndrome defined as having remnant functional jejunum intestine that is inadequate to maintain nutrient and hydration without the need for intravenous or enteral supplementation.

ORIGINAL EFFECTIVE DATE: 04/01/2019 | ARCHIVE DATE: | LAST REVIEW DATE: 02/20/2025 | LAST CRITERIA REVISION DATE: 02/16/2023

4. Individual is dependent on parenteral nutrition with documentation of **ALL** of the following:
    a. Has been dependent on parenteral nutrition/intravenous support for at least 12 months
    b. Requires three or more days per week of parenteral nutrition support
    c. Is unable to wean from parenteral nutrition

5. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:
    a. Baseline assessment of bilirubin, alkaline phosphatase, lipase, amylase
    b. **For adult patient:** Within 6 months prior to starting therapy, a colonoscopy of the entire colon has been done and any polyps found have been removed
    c. **For pediatric patient:** Within 6 months prior to starting therapy, fecal occult blood testing has been performed and for unexplained blood in the stool, colonoscopy/sigmoidoscopy has been performed

6. Individual does not have active gastrointestinal malignancy

7. Individual does not have biliary and/or pancreatic disease

8. There is no intestinal or stromal obstruction

9. Individual does not have severe hepatic impairment (Child-Pugh Class C)

10. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Gattex (teduglutide) and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Gastroenterologist

2. Individual's condition has responded while on therapy with response defined as **ONE** of the following:
    a. Achieved and maintains at least 20% decrease in weekly parenteral nutrition volume from baseline
    b. Achieved and maintains a decrease in the number of infusions per week from baseline

3. Individual has been adherent with the medication

4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
    a. Active gastrointestinal malignancy (GI tract, hepatobiliary, pancreatic)
    b. Colorectal cancer
    c. Small bowel cancer
    d. Unresolved intestinal or stromal obstruction
    e. Clinically meaningful cholecystitis, cholangitis, cholelithiasis, or pancreatitis
    f. Fluid overload and congestive heart failure

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

Gattex (teduglutide [rDNA origin]) for injection is indicated for the treatment of adults and pediatric patients 1 year of age (weighing at least 10 Kg) or older with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

SBS is a malabsorption disorder caused by the surgical removal of the small intestine, or rarely due to the complete dysfunction of a large segment of bowel. Most cases are acquired and usually do not develop SBS unless more than two thirds of the small intestine have been removed. The small intestine is about 6 meters (or 20 feet) long. The jejunum is about 2.5 meters long.

The gastrointestinal tract responds to massive resection with a process called intestinal adaptation, in which changes in intestinal morphology and function gradually increase absorptive capacity. Through this process, many patients eventually can transition from parenteral nutrition (PN) to full enteral feeds, and some even achieve full oral feeding.

SBS-associated intestinal failure reverses completely in approximately 50% of adults within the first two years. Thereafter, intestinal adaptation occurs in only a minority of patients. In the absence of additional intervention these patients remain dependent on chronic parenteral nutrition.

Teduglutide is an analog of naturally occurring human glucagon-like peptide-2 (GLP-2), which is secreted by L-cells of the distal intestine. Teduglutide binds to the glucagon-like peptide-2 receptors located in intestinal subpopulations. Activation of these receptors results in the local release of multiple mediators. Teduglutide is proven to enhance gastrointestinal fluid (wet weight) absorption and increase villus height and crypt depth of the intestinal mucosa. Teduglutide should be used in patients unable to be weaned from parenteral nutrition.

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Teduglutide has the potential to cause hyperplastic changes including neoplasia. Before initiating treatment with Gattex, a colonoscopy of the entire colon with removal of polyps should be done within 6 months prior to starting treatment and repeated in 1 year.

Patients with active gastrointestinal malignancy (GI tract, hepatobiliary, pancreatic), teduglutide therapy should be discontinued. The clinical decision to continue teduglutide in patients with non-gastrointestinal malignancy should be made based on risk and benefit considerations. In cases with a diagnosis of colorectal cancer, teduglutide therapy should be discontinued.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Resources:

Gattex (teduglutide) product information, revised by Takeda Pharmaceuticals America, Inc. 09-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 25, 2024.

DiBaise JK. Pathophysiology of short bowel syndrome. In: UpToDate, Lamont JT, Hoppin AG (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through November 2024. Topic last updated April 15, 2023. Accessed December 31, 2024.

DiBaise JK. Management of the short bowel syndrome in adults. In: UpToDate, Lamont JT, Robson KM (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through November 2024. Topic last updated February 06, 2023. Accessed December 31, 2024.

Stamm DA, Duggan C. Management of short bowel syndrome in children. In: UpToDate, Jensen C, Hoppin AG (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through November 2024. Topic last updated October 16, 2024. Accessed December 31, 2024.