

## PHARMACY COVERAGE GUIDELINE

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

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#### **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/or 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](http://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](mailto:Pharmacyprecert@azblue.com).

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### **Medical Necessity Requirements for GATTEX (teduglutide [recombinant deoxyribonucleic acid origin])**

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#### **Criteria for Initial Therapy:**

##### **Prescriber Qualifications**

- Prescribed by a Gastroenterologist or is in consultation with a Gastroenterologist

##### **Indication**

- Short bowel syndrome with dependence on parenteral support

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#### Age Requirement

- 1 year of age or older weighing at least 10 kilograms

#### Baseline Clinical Evaluation

- There is documentation of remnant functional jejunum intestine that is inadequate to maintain nutrient and hydration without intravenous or enteral supplementation
- Dependent on parenteral nutrition with documentation of **ALL** of the following:
  - Parenteral nutrition or intravenous support for at least 12 months
  - Requires parenteral nutrition support three or more days per week
  - Unable to wean from parenteral nutrition
- Completed **ALL** of the following baseline tests before starting treatment and will have continued monitoring as clinically appropriate:
  - Bilirubin, alkaline phosphatase, lipase, amylase
  - **For adult:** Colonoscopy and upper gastrointestinal endoscopy within 6 months prior to initiation with removal of any polyps
  - **For pediatric:** Fecal occult blood testing within 6 months prior to initiation; if new or unexplained blood in stool, colonoscopy or sigmoidoscopy is performed

#### Safety

- There are **NONE** of the following:
  - Active gastrointestinal malignancy (gastrointestinal tract, hepatobiliary, pancreatic)
  - Biliary or pancreatic disease
  - Intestinal or stromal obstruction
  - Severe hepatic impairment (Child Pugh Class C)

#### Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

#### Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results (bilirubin, alkaline phosphatase, lipase, amylase)
  - Supporting clinical documentation

#### Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

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#### Criteria for Continuation of Therapy (renewal therapy):

**Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.**

#### Prescriber Qualifications

- Continues to be seen by a Gastroenterologist or is in consultation with a Gastroenterologist

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#### Clinical Response

- Positive clinical response defined as **ONE** of the following:
  - Achieved and maintains at least 20 percent decrease in weekly parenteral nutrition volume from baseline
  - Achieved and maintains a decrease in number of infusions per week from baseline

#### Adherence

- Adherence to the prescribed therapy regimen has been documented

#### Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

#### Safety

- There are **NONE** of the following:
  - Active gastrointestinal malignancy (gastrointestinal tract, hepatobiliary, pancreatic)
  - Biliary or pancreatic disease
  - Intestinal or stromal obstruction
  - Severe hepatic impairment (Child Pugh Class C)
  - Colorectal cancer
  - Small bowel cancer
  - Clinically meaningful cholecystitis, cholangitis, cholelithiasis, or pancreatitis
  - Fluid overload and congestive heart failure

#### Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in short bowel syndrome
- Lab values confirming safe use (bilirubin, alkaline phosphatase, lipase, amylase)

#### Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year
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### Criteria for Off-Label Use Requests:

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

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#### **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.

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.

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#### **Definitions:**

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

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#### **Resources:**

Gattex (teduglutide) product information, revised by Takeda Pharmaceuticals America, Inc. 09-2025. Available at DailyMed  
<http://dailymed.nlm.nih.gov>. Accessed November 03, 2024.



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DiBaise JK. Pathophysiology of short bowel syndrome. In: UpToDate, Lamont JT, Cole CR, Hoppin AG (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through December 2025. Topic last updated January 05, 2026. Accessed January 19, 2026.

DiBaise JK. Management of the short bowel syndrome in adults. In: UpToDate, Lamont JT, Meyer C (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through December 2025. Topic last updated March 14, 2025. Accessed January 19, 2026.

Stamm DA, Duggan C. Management of short bowel syndrome in children. In: UpToDate, Cole CR, Hoppin AG (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through December 2025. Topic last updated March 21, 2025. Accessed January 19, 2026.

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