



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 4/01/2019
LAST REVIEW DATE: 2/18/2021
LAST CRITERIA REVISION DATE: 2/18/2021
ARCHIVE DATE:

GATTEX® (teduglutide [rDNA origin]) subcutaneous injection

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** Gattex (teduglutide) is 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 year of age or older weighing at least 10 Kg
 3. A confirmed diagnosis of short bowel syndrome defined as having less than 200 cm of remnant functional jejunum intestine
 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. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring 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. Does not have active gastrointestinal malignancy
 7. Does not have biliary and/or pancreatic disease
 8. There is no intestinal or stromal obstruction
 9. Does not have severe hepatic impairment (Child-Pugh Class C)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Gattex (teduglutide) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
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 responded while on therapy
 - a. Response is defined as **ONE** of the following:



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- i. Achieved and maintains at least 20% decrease in weekly parenteral nutrition volume from baseline
 - ii. Achieved and maintains a decrease in the number of infusions per week from baseline
3. Colonoscopies are being done according to current guideline recommendations
4. Individual has been adherent with the medication
5. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
 - a. Significant adverse effect such as:
 - i. Unresolved intestinal or stromal obstruction
 - ii. Fluid overload and congestive heart failure
 - iii. Active gastrointestinal malignancy
 - iv. Biliary and/or pancreatic disease

Renewal duration: 12 months

- Gattex (teduglutide) for all other indications not previously listed is considered **experimental or investigational** and will not be covered when any one or more of the following criteria are met:
1. Lack of final approval from the Food and Drug Administration;
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes;
 3. Insufficient evidence to support improvement of the net health outcome;
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; **or**
 5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, but are not limited to:

- Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration.

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-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



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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.

Definitions:

Short Bowel Syndrome (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 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.

Resources:

Gattex (teduglutide) product information, revised by Shire-NPS Pharmaceuticals, Inc. 06-2019, at DailyMed <http://dailymed.nlm.nih.gov> accessed January 27, 2021.

DiBaise JK. Pathophysiology of short bowel syndrome. In: UpToDate, Lamont JT, Motil KJ, Hoppin AG (Eds), UpToDate, Waltham MA.: UpToDate Inc. <http://uptodate.com>. Accessed on January 27, 2021.

DiBaise JK. Management of the short bowel syndrome in adults. In: UpToDate, Lamont JT, Grover S (Eds), UpToDate, Waltham MA.: UpToDate Inc. <http://uptodate.com>. Accessed on January 27, 2021.

Stamm DA, Duggan C. Management of short bowel syndrome in children. In: UpToDate, Jensen C, Motil KJ, Hoppin AG (Eds), UpToDate, Waltham MA.: UpToDate Inc. <http://uptodate.com>. Accessed on January 27, 2021.
