BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 4/1/19
LAST REVIEW DATE: 2/21/19
LAST CRITERIA REVISION DATE:
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.

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.**

GATTEX® (teduglutide [rDNA origin]) subcutaneous injection (cont.)

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 or is in consultation with a Gastroenterologist
  2. Individual is 18 years of age or older
  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:
     - Has been dependent on continuous parenteral nutrition support for at least 12 months
     - Requires three or more days per week of parenteral nutrition support
  5. Does not have active gastrointestinal malignancy
  6. Does not have biliary and/or pancreatic disease
  7. There is no intestinal or stromal obstruction
  8. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     - Baseline bilirubin, alkaline phosphatase, lipase, amylase
     - A colonoscopy of the entire colon has been done and any polyps found have been removed

  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 or is in consultation with a Gastroenterologist
  2. Individual's condition responded while on therapy
     - Response is defined as **ONE** of the following:
       - Achieved and maintains at least 20% decrease in weekly parenteral nutrition volume from baseline
       - Achieved and maintains a decrease in the number of infusions per week from baseline
  3. Does not have active gastrointestinal malignancy
  4. Does not have biliary and/or pancreatic disease

GATTEX® (teduglutide [rDNA origin]) subcutaneous injection (cont.)

5. Colonoscopies are being done according to current guideline recommendations

6. Individual has been adherent with the medication

7. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
    - Significant adverse effect such as:
        - Unresolved intestinal or stromal obstruction
        - Fluid overload and congestive heart failure

Renewal duration: 12 months

- Gattex (teduglutide) for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

1. Lack of final approval from the Food and Drug Administration, and
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
3. Insufficient evidence to support improvement of the net health outcome, and
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to*:
- Treatment with dosing or frequency outside the FDA-approved dosing and frequency

Description:

Gattex (teduglutide [rDNA origin]) for injection is indicated for the treatment of adults 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 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.

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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.

Resources:

Gattex (teduglutide) product information accessed 12-26-18 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=66b69c1e-b25c-44d3-b5ff-1c1de9a516fa

Jeppesen PB, Gilroy R, Pertkiewicz M, Allard JP, Messing B, O'Keefe SJ. Randomised placebo-controlled trial of teduglutide in reducing parenteral nutrition and/or intravenous fluid requirements in patients with short bowel syndrome. *Gut.* Jul 2011;60(7):902-914.

Jeppesen PB, Pertkiewicz M, Messing B, et al. Teduglutide reduces need for parenteral support among patients with short bowel syndrome with intestinal failure. *Gastroenterology.* Dec 2012;143(6):1473-1481 e1473.

UpToDate: Management of the short bowel syndrome in adults. Current through Nov 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/management-of-the-short-bowel-syndrome-in-adults?search=short%20bowel%20syndrome&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

UpToDate: Pathophysiology of short bowel syndrome. Current through Nov 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/pathophysiology-of-short-bowel-syndrome?search=short%20bowel%20syndrome&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

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Office notes, labs, and medical testing relevant to the request that show medical justification are required.