Pharmacy Policy Bulletin

Title:	Teduglutide (Gattex®)
Policy #:	Rx.01.127

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **teduglutide (Gattex®)** as provided under the member's prescription drug benefit.

Description:

Short bowel syndrome (SBS) is a malabsorptive condition most commonly caused by resection of the small intestine. It is defined not by the length resected bowel, but upon degree of intestinal dysfunction (ie significant malabsorption of both macronutrients and micronutrients).

Teduglutide is an analog of naturally occurring human glucagonlike peptide-2, a peptide secreted by L-cells of the distal intestine. Glucagonlike peptide-2 is known to increase intestinal and portal blood flow and inhibit gastric acid secretion. Teduglutide binds to the glucagonlike peptide-2 receptors located in intestinal subpopulations of enteroendocrine cells, subepithelial myofibroblasts, and enteric neurons of the submucosal and myenteric plexus. Activation of these receptors results in the local release of multiple mediators, including insulin-like growth factor-1, nitric oxide, and keratinocyte growth factor.

Teduglutide (Gattex®) is indicated for the treatment of adults and pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

Policy:

INITIAL CRITERIA Teduglutide (Gattex®) is approved when ALL of the following are met:

1. Diagnosis of Short Bowel Syndrome (SBS) (defined as a member left with <200 cm of functional small bowel); and
2. Currently receiving parental support at least three times per week; and
3. Prescribed by or in consultation with a gastroenterologist

Initial authorization: 6 months

REAUTHORIZATION CRITERIA Teduglutide (Gattex®) is re-approved when BOTH of the following are met:

1. Documentation of reduction in parenteral support from baseline (prior to initiation of teduglutide therapy); and
2. Prescribed by or in consultation with a gastroenterologist

Reauthorization: 2 years

Black Box Warning as shown in the drug Prescribing Information:

None

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

DiBaise JK. Pathophysiology of short bowel syndrome. UpToDate. July 2018. Available at: https://www.uptodate.com/contents/pathophysiology-of-short-bowel-syndrome?source=search_result&search=short%20bowel%20syndrome&selectedTitle=2~150. Accessed March 18,2021.

Gattex® (teduglutide) [prescribing information]. Lexington, MA. Shire-NPS Pharmaceuticals, Inc. January 2021. Available at: https://www.shirecontent.com/PI/PDFS/Gattex_USA_ENG.pdf . Accessed March 18,2021.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Gattex®	Teduglutide

Cross References:

Off Label Use Rx.01.33

Policy Version Number:	9.00
P&T Approval Date:	March 18, 2021
Policy Effective Date:	July 01, 2021
Next Required Review Date:	March 18, 2022