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5.50.003

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Gastrointestinal Agents	**Original Policy Date:**	June 28, 2013
Subject:	Gattex	**Page:**	1 of 5

Last Review Date: June 13, 2024

Gattex

Description

Gattex (teduglutide)

Background
Gattex is used to treat patients with short bowel syndrome (SBS) who need additional nutrition from intravenous feeding (parenteral nutrition). SBS is a condition that results from the partial or complete surgical removal of the small and/or large intestine. Extensive loss of the small intestine can lead to poor absorption of fluids and nutrients from food needed to sustain life. As a result, patients with SBS often receive parenteral nutrition. Gattex is an injection administered once daily that helps improve intestinal absorption of fluids and nutrients, reducing the frequency and volume of parenteral nutrition (1).

Regulatory Status
FDA-approved indication: Gattex (teduglutide [rDNA origin]) for injection is a glucagon-like peptide-2 (GLP-2) analog indicated for the treatment of patients 1 year of age and older with Short Bowel Syndrome (SBS) who are dependent on parenteral support (1).

Gattex 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. A follow-up colonoscopy (or alternate imaging) is recommended after 1 year. Gattex therapy should be discontinued in patients with active gastrointestinal malignancy (GI tract, hepatobiliary, pancreatic). The clinical decision to continue Gattex in patients with non-gastrointestinal malignancy should be made based on risk and

benefit considerations. In case of diagnosis of colorectal cancer, Gattex therapy should be discontinued (1).

In patients who develop intestinal or stomal obstruction, Gattex should be temporarily discontinued pending further clinical evaluation and management. Gattex may be restarted when the obstructive presentation resolves, if clinically indicated (1).

Cholecystitis, cholangitis, cholelithiasis, and pancreatitis have been reported. Patients should undergo laboratory assessment (bilirubin, alkaline phosphatase, lipase, and amylase) within 6 months prior to starting Gattex, and at least every 6 months while on Gattex. If clinically meaningful changes are seen, further evaluation is recommended including imaging, and continued treatment with Gattex should be reassessed (1).

There is a potential for fluid overload and congestive heart failure while on Gattex. If fluid overload occurs, especially in patients with cardiovascular disease, parenteral support should be appropriately adjusted, and Gattex treatment reassessed (1).

Safety and efficacy in patients less than 1 years of age have not been established (1).

Related policies
Zorbtive

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Gattex may be considered **medically necessary** if the conditions indicated below are met.

Gattex may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 1 year of age or older

Diagnosis

Patient must have the following:

Short bowel syndrome (SBS)

AND ALL of the following:

1. Concurrent parenteral support
2. Colonoscopy (or alternate imaging) performed in the past 6 months (N/A if colon has been removed)
3. Absence of gastrointestinal malignancy
4. Baseline bilirubin, alkaline phosphatase, lipase, amylase levels and every six months thereafter
5. Patient age 1-17 **ONLY**: prescriber agrees to perform fecal occult blood testing annually

Prior – Approval *Renewal* Requirements

Age 1 year of age or older

Diagnosis

Patient must have the following:

Short bowel syndrome (SBS)

AND ALL of the following:

1. Concurrent parenteral support
2. Absence of gastrointestinal malignancy
3. Absence of intestinal or stomal obstruction
4. Bilirubin, alkaline phosphatase, lipase, and amylase levels to be obtained every six months
5. Documentation of a decreased need in volume of intravenous parenteral nutrition and number of infusion days per week
6. Patient age 1-17 **ONLY**: prescriber agrees to perform fecal occult blood testing annually

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Gattex is indicated for the treatment of patients with short bowel syndrome (SBS) who are dependent on parenteral support. Patients treated with Gattex have a potential increased risk of developing cancer and abnormal growths (polyps) in the intestine, obstructions in the intestine, gallbladder disease, biliary tract disease and pancreatic disease. Prior to initiation of therapy, patients must have a recent (within 6 months) colonoscopy (or alternate imaging) and a laboratory assessment of bilirubin, alkaline phosphatase, lipase, and amylase levels. For continuation of therapy, patients must have shown a decreased need in volume of intravenous parenteral nutrition and number of infusion days per week and laboratory assessments every 6 months. Safety and efficacy in pediatric patients less than 1 year of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Gattex while maintaining optimal therapeutic outcomes.

References

1. Gattex [Package Insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; February 2024.

Policy History

Date	Action
June 2013	Addition to PA
September 2014	Annual criteria review
September 2015	Annual criteria review
September 2016	Annual editorial review and reference update Policy number changed from 5.09.03 to 5.50.03
March 2017	Annual review and reference update
March 2018	Annual editorial review Addition of alternative imaging [other than colonoscopy] to initiation requirements

March 2019	Annual review and reference update
June 2019	Reduced age requirement to 1 year and older. Added pediatric requirement for fecal occult blood testing
September 2019	Annual review
March 2020	Annual review and reference update
June 2021	Annual review and reference update
June 2022	Annual review
June 2023	Annual review and reference update. Changed policy number to 5.50.003
June 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.