BlueCross BlueShield Federal Employee Program

GATTEX (teduglutide)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.