BlueCross BlueShield of Alabama

Gattex® (teduglutide) Prior Authorization Criteria Program Summary

This prior authorization program applies to Commercial, NetResults A series, SourceRx and Health Insurance Marketplace formularies.

OBJECTIVE

The intent of the Gattex (teduglutide) Prior Authorization (PA) program is to appropriately select patients for treatment according to product labeling and/or clinical studies and/or clinical practice guidelines. The PA criteria consider Gattex appropriate for use in patients who: a) have been diagnosed with short bowel syndrome, b) are dependent on parenteral nutrition, c) have had a colonoscopy and polyps removed, if present, prior to initiating therapy, and d) do not have any FDA labeled contraindications to therapy. Renewal criteria require patients to have at least a 20% reduction in parenteral nutrition/intravenous fluid from baseline. Dosing is restricted to FDA labeled dosing of 0.05 mg/kg/day.

TARGET DRUGS

Gattex® (teduglutide)

Brand (generic)	GPI	Multisource Code
Gattex® (teduglutide)		
5 mg single use vial kit (1 vial/kit)	52533070006420	M, N, O, or Y
5 mg single use vial kit (30 vials/kit)	52533070006420	M, N, O, or Y

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Gattex will be approved for INITIAL use when ALL of the following are met:

1. The patient has a diagnosis of short bowel syndrome (SBS)
   AND
2. The patient is currently receiving parenteral nutrition/intravenous fluids (PN/IV) at least 3 days per week
   AND
3. The patient has had a colonoscopy with any polyps removed, if present, within the last 6 months
   AND
4. The patient does not have any FDA labeled contraindications to therapy
   AND
5. The dose is within the FDA-labeled dose of 0.05 mg/kg/day

Length of Approval: 6 months

Gattex will be approved for RENEWAL when ALL of the following are met:

1. The patient has been previously approved through the Prime Therapeutics PA process
   AND
2. The patient has had at least a 20% reduction from baseline in PN/IV fluids
   AND
3. The patient does not have any FDA labeled contraindications to therapy
   AND
4. The dose is within the FDA-labeled dose of 0.05 mg/kg/day

Length of Approval: 12 months

Agent	Contraindication(s)
Gattex (teduglutide)	None

This pharmacy policy is not an authorization, certification, explanation of benefits or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All pharmacy policies are based on (i) information in FDA approved package inserts (and black box warning, alerts, or other information disseminated by the FDA as applicable); (ii) research of current medical and pharmacy literature; and/or (iii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

The purpose of Blue Cross and Blue Shield of Alabama's pharmacy policies are to provide a guide to coverage. Pharmacy policies are not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.

FDA APPROVED INDICATIONS AND DOSAGE[1]

Agent	Indication	Dose
Gattex (teduglutide)	Short Bowel Syndrome (SBS) in adult patients who are dependent of parenteral support	**SBS:** 0.05 mg/kg once daily

CLINICAL RATIONALE[2,3]

SBS is a result of either surgical resection or congenital defects. Patients with SBS have an inability to maintain protein, fluid, electrolyte, and micronutrient balance. These patients are prone to malnutrition, diarrhea, dehydration, and an inability to maintain weight. Patients often require long-term parenteral nutrition (PN) or intravenous fluids (IV). These therapies come with significant complications and require frequent monitoring of liver function, vitamin, mineral, and trace element levels.

Clinical care of SBS patients mainly focuses on optimizing intestinal function through oral rehydration, anti-diarrheal agents, anti-secretory agents, growth hormone, glutamine and dietary intervention. There are surgical procedures (e.g. bowel lengthening or intestinal transplant) utilized in the management of SBS but these procedures are associated with significant morbidity and mortality and are only considered for select patients.

Short term outcomes for patients maintained on PN/IV are pretty good. However over time patients can lose venous access or develop septic complications. The use of pharmacologic therapies to decrease the need for PN/IV has shown good results in this patient population.

EFFICACY[1]

The safety and efficacy of teduglutide was evaluated in 4 clinical studies; 2 placebo controlled and 2 extension studies. Study 1 with the open-label extension Study 2 was in adults with SBS who were dependent on PN/IV for at least 12 months and required PN at least 3 times per week. Patients were randomized to placebo (n=43) or teduglutide (n=43) at 0.05 mg/kg/day for 24 weeks. Clinical assessments and volume adjustments (up to 30% decrease) were done at weeks 2, 4, 8, 12, 20, and 24. The primary efficacy endpoint was based on clinical response, defined as at least a 20% reduction in weekly PN/IV volume from baseline to both Weeks 20 and 24. In this trial 63% (27/43) of treated patients and 30% (13/43) of placebo treated patients were considered responders (p=0.002). The mean reduction at Week 24 in PN/IV volume was 4.4 L for teduglutide treated (pre-treatment baseline of 12.9 L/week) versus 2.3 L for placebo treated (pre-treatment baseline of 13.2 L/week) patients from baseline. In the extension Study 2, of the responders from Study 1 who entered Study 2 100% (25/25) sustained their response to teduglutide after one year of continuous treatment. A 20% or > reduction of PN was achieved in 72% (31/43) patients after an additional 28 weeks of therapy. The study results for Study 3 and 4 were similar.

SAFETY

The most common adverse events (≥10%) across all studies are abdominal pain, injection site reactions, nausea, headaches, abdominal distension, and upper respiratory tract infection. Vomiting and fluid overload were also reported in Study 1 and 3 at the same rate.

Teduglutide is associated with acceleration of neoplastic growths including small bowel neoplasia and colorectal polyps. Due this risk, a colonoscopy of the entire colon should be done within 6 months prior to starting therapy. If polyps are present, they should be removed at least 6 months prior to starting treatment with teduglutide.[1]

Teduglutide has the potential to increase absorption of concomitant oral medications. Agents that require titration or have a narrow therapeutic index require careful monitoring and possible dose adjustments.

REFERENCES

1. Gattex prescribing information. NPS Pharmaceuticals, Bedminster NJ. July 2016.
2. Cagir, Burt. Short-Bowel Syndrome Treatment & Management. Medscape. December 2012. Available at: http://emedicine.medscape.com/article/193391-treatment. Accessed 2/6/13.
3. FDA Summary Review. Gattex. Available at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist. Accessed 2/6/13.