Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	February 6, 2013 November 2014

GATTEX® (teduglutide)

LENGTH OF AUTHORIZATION: Up to one year

CLINICAL NOTES: Teduglutide is a human recombinant version of endogenous glucagon-like peptide 2 (GLP-2). Patients with short bowel syndrome-intestinal failure (SBS-IF) experience a reduction in intestinal absorptive capacity following surgical bowel resection. Intestinal failure can lead to severe malabsorption, diarrhea, electrolyte disturbances, weight loss and malnutrition. GLP-2 is one of several endogenous factors involved in the normal growth and maintenance of the intestinal epithelium. The use of teduglutide has been shown to reduce the parenteral nutrition/IV fluid requirements in patients with SBS-IF.

INITIAL REVIEW CRITERIA (ALL OF THE FOLLOWING MUST BE TRUE):

- Patient must be ≥18 years old.
- Patient must have a diagnosis of short bowel syndrome-intestinal failure (SBS-IF)
- Patient must be currently receiving parenteral nutrition or IV fluids on an ongoing basis; patient must have required parenteral nutrition or IV fluids at least three times weekly for a minimum of 12 months (verified by supporting documentation) (Optimization of adjunctive medications and dietary modifications can achieve adequate intestinal rehabilitation in many patients and should be tried prior to initiating teduglutide)

REVIEW FOR CONTINUATION OF APPROVAL:

- Patient is still requiring parenteral nutrition/IV fluids but must have achieved a minimum of a 20 percent reduction in the volume of parenteral support since the implementation of teduglutide therapy (verified by supporting documentation)
- At this time, there is insufficient clinical information to determine if patients who have successfully been weaned completely off parenteral support need to continue teduglutide therapy.

DOSING & ADMINISTRATION:

- Maximum dose of 0.05 mg/kg/day once daily
- Reduce dose by 50 percent for CLcr < 50mL/min
- Administer by subcutaneous injection; alternate sites between one of the four quadrants of the abdomen, or into alternating thighs or alternating arms
- Dosage Form: 5 mg powder for injection to be reconstituted with 0.5 mL sterile water for injection provided in prefilled syringe
- Use within three hours of reconstitution