Protocol for Gattex® (teduglutide)

Approved January 2023

Background: *Short bowel syndrome (SBS) is a condition that results from surgical resection or congenital disease of the small intestine which is characterized by the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balances when on a conventionally accepted, normal diet.*

Gattex *is as a glucagon-like peptide-2 (GLP-2) analog indicated for the treatment of patients with SBS who are dependent on parenteral support.*

Criteria for approval:

1. Patient has a documented diagnosis of SBS defined as < 200 cm of viable small bowel.
2. Patient is 1 year of age or older and is dependent on parenteral nutrition support.
3. Patient is (an adult) dependent on parenteral nutrition/intravenous (PN/I.V.) support.
    a. For at least 12 months; **AND**
    b. Requires at least 3 times per week of parenteral nutrition support; **OR**
4. The following baseline tests have been completed before initiation of treatment:
    a. Whitin 6 months prior to initiating therapy, perform bilirubin, alkaline phosphatase, lipase, and amylase tests.
    b. For adult patients: within 6 months prior to initiating therapy, perform a colonoscopy with removal of polyps if applicable.
    c. For pediatric patients: within 6 months prior to initiating therapy, perform fecal occult blood test; if there is unexplained blood in the stool, perform colonoscopy/sigmoidoscopy.
5. Medication is prescribed by or in consultation with a gastroenterologist or a provider specializing in the patient's diagnosis.
6. Weight will be monitored.
7. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence.

Initial Approval: 6 months

Continuation of therapy:

1. Patient is responding to therapy, defined as:
    a. Achieving at least 20% reduction in weekly PN/I.V. from baseline; **OR**
    b. Decrease in weekly PN/I.V. volume.
2. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence.

Renewal Approval: 12 months

References:

1. Gattex [prescribing information]. Takeda Pharmaceuticals America, Inc. Lexington, MA 02421. October 2022
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2019. Updated periodically
3. Cagir, B. (2021, February 16). Short-Bowel Syndrome. Medscape. Accessed November 18, 2022 at: https://emedicine.medscape.com/article/193391-overview
4. Guillen G and Atherton NS. ; Nichole S. Atherton. Short Bowel Syndrome. Stat Pearls, July 26, 2022. Accessed November 21, 2022 at: https://www.ncbi.nlm.nih.gov/books/NBK536935/