RX.PA.010.MPC Gattex® (Teduglutide)

The purpose of this policy is to define the prior authorization process for Gattex® (teduglutide).

Gattex® (teduglutide) is an analog glucagon-like peptide 2 (GLP-2) indicated for the treatment of short bowel syndrome in patients dependent on parenteral nutrition support.

The drug, Gattex® (teduglutide), is subject to the prior authorization process.

PROCEDURE

A. Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a gastroenterologist
- Must be age 1 year and older
- Must have a diagnosis of short bowel syndrome defined as follows:
  - Must have <200 cm of residual functional small intestine
- Must provide date of bowel resection
- Must be receiving parenteral or intravenous nutrition support (PN/IV) at least 3 times weekly
  - Must provide baseline PN/IV schedule (frequency and volume)
- Must have undergone a colonoscopy prior to treatment (within 6 months), where appropriate
- Must have had recent (within 6 months) baseline laboratory testing of bilirubin, alkaline phosphatase, lipase, and amylase
- Must not have an active intestinal obstruction
- Must not have an active malignancy

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Gattex will be considered investigational or experimental for any other use and will not be covered.

D. Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

- Documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy, including documentation that member has weaned off or decreased PN/IV requirements
- Documentation from the prescriber that the patient is undergoing laboratory testing of bilirubin, alkaline phosphatase, lipase, and amylase at least every 6 months during treatment with Gattex
- Documentation from the prescriber that the patient has had a colonoscopy, if appropriate, within the recommended time frame during treatment with Gattex:
    - After 1 year of treatment
    - At least every 5 years after the first year
- Documentation from the prescriber that the member does not have an active intestinal obstruction or active malignancy

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year
Quantity Level Limit	
Gattex	30 vials per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

HCPCS Code(s):

Code	Description
J3490	Unclassified drugs
J3590	Unclassified biologics

REFERENCES

1. Gattex [prescribing information]. Hospira, Inc. McPherson, KS. December 2012.
2. Jeppesen PB, Gilroy R, Pertkiewicz, et al. Randomised placebo-controlled trial of teduglutide in reducing parenteral nutrition and/or intravenous fluid requirements in patients with short bowel syndrome. Gut 2011; 60(7): 902-914.
3. Jeppesen PB, Pertkiewicz M, Messing B, et al. Teduglutide reduces need for parenteral support

among patients with short bowel syndrome with intestinal failure. Gastroenterology 2012; 143: 1473-1481.
4. American Gastroenterological Association Medical Position Statement: Short Bowel Syndrome and Intestinal Absorption. Gastroenterology 2003;124(4):1105–1110.
5. Seidner DL, Schwartz LK, Winkler MF, et al. Increased Intestinal Absorption in the Era of Teduglutide and Its Impact on Management Strategies in Patients with Short Bowel SyndromeAssociated Intestinal Failure. J Parenter Enteral Nutr 2013. http://pen.sagepub.com/content/early/2013/01/22/0148607112472906. Accessed 28 January 2013.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/2022*
Addition of dosing requirements and off-label restriction	*12/2021*
P&T Review	*11/2020*