Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Gattex (teduglutide)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2013 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

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.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

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

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a gastroenterologist
- Must be age 18 years 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 not have an active intestinal obstruction
- Must not have an active malignancy
- 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

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 member does not have an active intestinal obstruction or active malignancy
- 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 teduglutide (Gattex)
- Documentation from the prescriber that the patient has had a colonoscopy, if appropriate, within the recommended time frame during treatment with teduglutide (Gattex):

- After 1 year of treatment
- At least every 5 years after the first year

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.

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 Syndrome-Associated Intestinal Failure. *J Parenter Enteral Nutr* 2013. http://pen.sagepub.com/content/early/2013/01/22/0148607112472906. Accessed 28 January 2013.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED

Annual review	*02/17, 02/18*