Gattex (teduglutide)

Line(s) of Business: HMO; PPO; QUEST Integration
Effective Date: 10/01/2015
Akamai Advantage

POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
- Treatment of adult patients with short bowel syndrome (SBS) who are dependent on parenteral support

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
- Initial therapy
  - Documentation of member’s requirement of parenteral support
  - For SBS due to Crohn’s disease: documentation of clinical remission of Crohn’s disease
- Continuation of therapy
  - Documentation of reduction in parenteral support since the initiation of Gattex therapy

C. EXCLUSIONS
- Age < 18 years
- Cancer within the last 5 years
- Body mass index (BMI) is < 15 kg/m²
- Received human growth hormone (e.g., Zorbtive®) within the last 6 months
- Four or more SBS-related hospital admissions within the last 12 months
- Hospital admission within the last 30 days
- For member with inflammatory bowel disease (IBD)
  - Introduction or change in an immunosuppressant therapy for IBD within the last 3 months
  - Introduction or change in a biologic agent for IBD within the last 6 months

D. CRITERIA FOR APPROVAL
1. Short bowel syndrome (SBS)
   Authorizations of 6 months may be granted to member who has required parenteral support for at least 3 times a week for a period of at least 12 continuous months prior to Gattex therapy initiation.
2. **Short bowel syndrome (SBS) due to Crohn’s disease**
Authorizations of 6 months may be granted to member who has required parenteral support for at least 3 times a week for a period of at least 12 continuous months prior to Gattex therapy initiation AND member must be in clinical remission for greater than or equal to 12 weeks prior to Gattex therapy initiation.

E. **CONTINUATION OF THERAPY**
1. **Short bowel syndrome (SBS)**
Authorization of 6 months may be granted to members requesting authorization for continuation of therapy when ALL of the following criteria are met:
   a. Requirement for parenteral support has decreased from baseline while on Gattex therapy.
   b. Previous Gattex therapy was authorized by HMSA or member meets all initial criteria.

F. **DOSAGE AND ADMINISTRATION**
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

G. **IMPORTANT REMINDER**
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

H. **REFERENCES**