Drug Therapy Guidelines

Gattex® (teduglutide [rDNA origin])

<table>
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<tr>
<th>Medical Benefit</th>
<th>Effective: 11/15/19</th>
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<td>Pharmacy- Formulary 1</td>
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<td>Pharmacy- Formulary 2</td>
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<td>Pharmacy- Formulary 3/Exclusive</td>
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<td>Pharmacy- Formulary 4/AON</td>
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I. Medication Description

Teduglutide is a recombinant glucagon-like peptide-2 (GLP-2) analog, which improves bowel function by enhancing absorption of nutrients and fluids, and decreases dependence on parenteral nutrition. Endogenous GLP-2, a gastrointestinal, trophic hormone, is involved in the repair and regeneration of intestinal cells. Endogenous GLP-2 increases intestinal and portal blood flow while inhibiting gastric acid secretion, thereby reducing intestinal loss and improving intestinal absorption.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for all requests.

III. Policy

Coverage is provided when the following criteria are met:

- Prescribed for the treatment of members with Short Bowel Syndrome AND
- Member is 1 year of age or older AND
- Member is dependent on parenteral support AND
  - For members 18 years of age or older:
    - Member has been dependent on parenteral support for at least 12 months AND
    - Member requires parenteral nutrition at least 3 times per week AND
- Baseline weekly volume of parenteral support is submitted AND
- Member does not have active gastrointestinal malignancy.

IV. Quantity Limitations

Coverage is provided for the maximum dose of the medication (0.05mg/kg/day).

V. Coverage Duration

Initial coverage is granted for 6 months and may be renewed.

VI. Coverage Renewal Criteria

First renewal: coverage can be renewed in the presence of clinical benefit from therapy as evidenced by the following:

- Submission of chart notes documenting the member is still dependent on parenteral support AND
- At least a 20% reduction from baseline weekly volume of parenteral support has been achieved
Subsequent renewals: coverage can be authorized with the submission of chart notes documenting:

- The member is still dependent on parenteral support **AND**
- Continued clinical benefit is shown from Gattex.

VII. Billing/Coding Information

Gattex is available as vials containing 5mg powder for injection.

VIII. Summary of Policy Changes

- 9/15/13: moved from Abbreviated Criteria to own policy
- 9/15/14: maximum dose defined
- 7/1/15: formulary distinctions made
- 9/15/15: no policy changes
- 7/19/16: no policy changes
- 6/21/17: no policy changes
- 8/15/18:
  - added exclusion of coverage in member’s with active gastrointestinal malignancy
  - added dependence on parenteral support to coverage criteria
  - updated coverage duration
  - updated renewal criteria
- 8/15/19: no policy changes
- 11/15/19: updated criteria to include coverage for pediatric members

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.