**Medication Policy Manual**

**Policy No:** dru304  
**Date of Origin:** May 16, 2013  
**Committee Approval Date:** December 16, 2016  
**Next Review Date:** December 2017  
**Effective Date:** January 1, 2017

**IMPORTANT REMINDER**

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

*Benefit determinations should be based in all cases on the applicable contract language.* To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

**Description**

Teduglutide (Gattex) is a subcutaneous glucagon like peptide-2 molecule for treatment of dependence on parenteral nutrition in patients with short bowel syndrome.
Policy/Criteria

I. Most contracts require prior authorization approval of teduglutide prior to coverage. Teduglutide may be considered medically necessary when criteria A, B, and C, below are met.

A. Diagnosis of short bowel syndrome defined by clinical documentation of less than 200 cm of remnant functional intestine

AND

B. Clinical documentation of dependence on parenteral nutrition including:
   a. Two or more years of continuous parenteral nutrition support
   AND
   b. Three or more days per week of parenteral nutrition support
   AND

C. Clinical documentation of colonoscopy within six months prior to initiation of teduglutide to confirm absence of gastrointestinal malignancy.

II. Administration, Quantity Limitations, and Authorization Period

A. OmedaRx considers teduglutide to be a self-administered medication.

B. Authorization shall be reviewed as follows to confirm that medical necessity criteria are met and that the medication is effective.
   a. Initial authorization shall be reviewed at six months.
   b. Continued authorization or re-authorization (after the initial six-month period) shall be reviewed at least annually. Clinical documentation indicating a reduction in the numbers of days of required parenteral nutrition support, improvement in the amount of enteral nutrition intake and adequate assessment of malignancy risk must be provided.

III. Teduglutide is considered investigational when used for all other conditions, including but not limited to:

A. Crohn's Disease

Position Statement

- Short bowel syndrome occurs when, following surgical resection of some or the entire small and large intestine, a patient is left with < 200 cm of functional intestine causing significant malabsorption of both macro and micro-nutrients. [1]

- Following surgery, the remnant bowel begins to compensate and increase the surface area for absorption through intestinal adaptation. Intestinal adaptation can take up to two years in helping patients transition to enteral nutrition. [2,3]

- Evidence for teduglutide effectiveness is limited to patients who required at least three days per week of parenteral nutrition support to meet their energy requirements. [4,5]
- Teduglutide is associated with several significant concerns including, acceleration of neoplastic growth, intestinal obstruction, and biliary and pancreatic disease. Due to this risk, the FDA recommends colonoscopy of the entire colon prior to initiating treatment with teduglutide and after one year of treatment. Subsequent colonoscopies should be done as needed, but no less than every five years. [2,6]

- Teduglutide possesses a novel mechanism of action and is the first glucagon like peptide-2 molecule approved for use. However, it does not have a track record of safety evidence and its profile is still developing. [2,6]

Clinical Efficacy

Short Bowel Syndrome [2,4,5]

Teduglutide, when compared to placebo, demonstrated an ability to reduce the requirement for parenteral nutrition volume. However, there is no evidence that teduglutide is safer or more effective than other options and its effect is reversible.

- The efficacy of teduglutide was evaluated in two, double-blind randomized controlled trials.
  * The pivotal randomized controlled trial evaluated teduglutide versus placebo over 24 weeks to establish the proportion of patients who had a reduction of 20% to 100% in parenteral nutrition volume at week 24 when compared to baseline.
  * 63% of teduglutide patients met the primary endpoint compared to 30% of placebo patients, a statistically significant difference.
  * No patients in either treatment arm were weaned completely from parenteral nutrition support during the trial.
  * A supportive randomized controlled trial evaluated two separate doses of teduglutide versus placebo over 24 weeks to establish the number of patients who meet a pre-specified categorical reduction of parenteral nutrition volume.
  * The lower dose treatment arm of teduglutide demonstrated a significant difference in the proportion of patients achieving “response” as defined by the categorical reduction when compared to placebo. However, the higher dose did not demonstrate a significant difference when compared to placebo.
  * Two patients in the low-dose treatment arm were weaned completely from parenteral nutrition support during the trial.

Crohn’s Disease [7]

- Two phase II trials have evaluated teduglutide for treatment of Crohn’s disease.
- Preliminary data suggests that teduglutide may have some utility for treatment of Crohn’s disease when compared to placebo. However, larger, well-controlled trials are necessary to support the benefit of teduglutide in this population.
Safety [2,4,5]

- Several significant concerns exist in the evidence for safety of teduglutide including, acceleration of neoplastic growth, intestinal obstruction, and biliary and pancreatic disease.

- The most commonly reported adverse events (≥10%) in clinical trials with teduglutide include abdominal pain, upper respiratory tract infection, nausea, abdominal distension, vomiting, and fluid overload. For patients with a stoma, stoma complication (41%) was also commonly reported.

Cross References

<table>
<thead>
<tr>
<th>Growth Hormone, dru015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increlex, mecasermin, dru126</td>
</tr>
<tr>
<td>Self-Administered Injectables, dru110</td>
</tr>
</tbody>
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Codes

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<tr>
<th>Number</th>
<th>Description</th>
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References

1. Vanderhoof, JA. Management of the short bowel syndrome in adults. In: UpToDate, LaMont, JT (Ed), UpToDate, Waltham, MA, 2012.
2. Teduglutide (Gattex) Medical Review. [cited 12/18/2013]; Available from: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/203441Orig1s000MedR.pdf

Revision History

<table>
<thead>
<tr>
<th>Revision Date</th>
<th>Revision Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/16/2016</td>
<td>No changes to coverage criteria with this annual update.</td>
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<tr>
<td>01/08/2016</td>
<td>No changes to coverage criteria with this annual update.</td>
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