

Criteria Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

teduglutide (Gattex®)

Initial approval criteria: Non-formulary **teduglutide (Gattex®)** will be covered for 6 months on the prescription drug benefit when the following criteria are met:

- Prescribed by a Gastroenterologist
- AND-
- Patient is at least 18 years of age
- AND-
- Patient has diagnosis of short bowel syndrome
- AND-
- Patient is dependent on parenteral (nutrition or fluid) support
- AND-
- Patient has had a colonoscopy in the past 6 months
- AND-
- Intolerance or contraindication to, or failure (after adequate trial[^]) to all of the following:
 - i. Proton pump inhibitor (PPI)
 - ii. loperamide (up to 16 mg/day)
 - iii. codeine sulfate (up to 60 mg three times daily)
 - iv. octreotide 100 mcg given three times daily

Continued use criteria: Non-formulary **teduglutide (Gattex®)** will continue to be covered for 12 months on the prescription drug benefit when the following criteria are met:

- Patient continues to be under the care of a Gastroenterologist
- AND-
- Documented decreased need for parenteral support compared to baseline
- AND-
- if patient has a colon, is up to date with screening colonoscopies
 - o Colonoscopy due after 1 year of treatment of teduglutide, then every 5 years (or more frequent if polyps found)

Note:

[^] An adequate trial is considered at least 4 weeks of therapy.