Teduglutide (Gattex®)	Place of Service Home Infusion Administration HCPCS: J3490 NDCs: 68875-0102-1 [30 drug vial kits containing ancillary supplies and 30 single-dose vials of Gattex 5 mg (NDC 68875-0101-1)] 68875-0103-01 [5 mg one-vial kit containing ancillary supplies and one single-dose vial of 5 mg Gattex (68875-0101-1)]

Condition listed in policy (*see criteria for details*)

- Parenteral-Nutrition-Dependent Short-Bowel Syndrome

AHFS therapeutic class: SBS – GLP-2 analog

Mechanism of action: analog of naturally occurring human glucagon-like peptide-2 (GLP-2)

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Gattex® (teduglutide) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Parenteral-Nutrition-Dependent Short-Bowel Syndrome

1. Diagnosis is Short-Bowel Syndrome (SBS), **AND**
2. Patient has been dependent on parenteral nutrition for at least 3 months

Covered Doses

Up to 0.05 mg/kg SC daily

Coverage Period

Initial: six months.

Reauthorization: If patient has at least a 20% reduction in weekly PN/IV volume from baseline, cover every 6 months based upon continued response.

ICD-10:
K91.2

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Gattex® (teduglutide) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 5 mg (white, lyophilized powder in single-use glass vials). After reconstitution with 0.5 mL sterile water for Injection, a max of 3.8 mg of teduglutide can be delivered.

- Dispensed as either a one-vial kit (preassembled) or a 30-vial kit (assembled by a pharmacist).

- One-vial kits are pre-assembled and ready to be used:
  GATTEX 5 mg One-vial Kit (NDC 68875-0103-01):
  - One single-dose vial of 5 mg teduglutide (NDC 68875-0101-01)
  - One disposable prefilled syringe containing 0.5 mL Sterile Water for Injection USP for
  - reconstitution, with a separate needle (22G x 1½ in) to attach to the syringe
  - One sterile disposable 1-mL syringe with needle (26G x 5/8 in) for dosing
  - Four alcohol swabs

- The pharmacist's assembled 30-Vial Kit should contain the items:
  GATTEX 5 mg Strength 30-Vial Kit (NDC 68875-0102-1):
  - Thirty single-dose vials of 5 mg teduglutide (NDC 68875-0101-1)
  - Thirty disposable prefilled syringes containing 0.5 mL Sterile Water for Injection USP for reconstitution, with 30 separate needles (22G x 1½ in) to attach to the syringes
  - Thirty sterile disposable 1-mL syringes with needle (26G x 5/8 in) for dosing
  - Sixty alcohol swabs

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Gattex (teduglutide) [Prescribing Information]. Lexington, MA. Shire-NPS Pharmaceuticals, Inc. 1/2021.

(7) Policy Update

Date of last review: 1Q2023
Date of next review: 1Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee