blue california
Promise Health Plan

teduglutide (Gattex)

Medical Benefit Drug Policy

Place of Service

Home Infusion Administration

Drug Details

USP Category: GASTROINTESTINAL AGENTS

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

HCPCS:

J3490:Unclassified drugs

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

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

- Parenteral-Nutrition-Dependent Short-Bowel Syndrome

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

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The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Parenteral-Nutrition-Dependent Short-Bowel Syndrome

Meets medical necessity if all the following are met:

Initial

1. Patient has been dependent on parenteral nutrition for at least 3 months

Reauthorization

1. Patient has at least 20% reduction in weekly PN/IV volume from baseline

Covered Doses:

Not to exceed 0.05 mg/kg given subcutaneously daily

Coverage Period:

6 months

ICD-10:

K91.2

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Gattex (teduglutide) Prescribing Information. Takeda Pharmaceuticals America, Inc., Cambridge, MA: 9/2025.

Review History

Date of Last Annual Review: 1Q2026

Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee