

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1035-12
Program	Prior Authorization/Notification
Medication	Gattex [®] (teduglutide [rDNA origin]), for injection, for subcutaneous use
P&T Approval Date	2/2013, 11/2013, 11/2014, 11/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 9/2021, 9/2022, 9/2023, 9/2024
Effective Date	12/1/2024

1. Background:

Gattex[®] (teduglutide) is a glucagon-like peptide-2 (GLP-2) analog indicated for the treatment of adults and pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria^a:

A. Initial Authorization

1. **Gattex** will be approved based upon **both** of the following criteria:

a. Diagnosis of Short Bowel Syndrome (SBS)

-AND-

b. Dependent on parenteral support

Authorization will be issued for 12 months.

B. Reauthorization

1. **Gattex** will be approved based on the following criterion:

a. Documentation of positive clinical response to Gattex therapy

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. Reference:

1. Gattex [package insert]. Lexington, MA: Takeda Pharmaceuticals, Inc.; February 2024.

Program	Prior Authorization/Notification - Gattex (teduglutide [rDNA origin]) Notification
Change Control	
2/2013	New criteria.
11/2013	Formatting update. Removal of dose information in Background Section.
11/2014	Annual review. Increased reauthorization approval duration to 60 months.
11/2015	Annual review. Revised initial authorization criteria to remove 12 consecutive months of PN/IV support therapy.
9/2016	Annual review. Reduced reauthorization approval duration to 24 months. Updated reference.
9/2017	Annual review. No changes.
9/2018	Annual review. No changes.
9/2019	Annual review. Updated background and references. No changes to criteria.
9/2020	Annual review. No changes to criteria.
9/2021	Annual review with no changes to criteria. Updated references.
9/2022	Annual review. Added state mandate footnote. Updated reauthorization duration to the standard 12 months.
9/2023	Annual review with no changes to criteria. Updated reference.
9/2024	Annual review. Updated initial authorization duration to 12 months. Updated reference.