# AvMed

## PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

**Directions**: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

**Drug Requested: Gattex®** (teduglutide [rDNA Origin]) **Injection**

**MEMBER & PRESCRIBER INFORMATION:** Authorization may be delayed if incomplete.

**Member Name:** _____

**Member AvMed #:** _____ **Date of Birth:** _____

**Prescriber Name:** _____

**Prescriber Signature:** _____ **Date:** _____

**Office Contact Name:** _____

**Phone Number:** _____ **Fax Number:** _____

**DEA OR NPI #:** _____

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

**Drug Form/Strength:** _____

**Dosing Schedule**: _____ **Length of Therapy**: _____

**Diagnosis:** _____ **ICD Code, if applicable:** _____

**Weight:** _____ **Date:** _____

**Final dose per day:** _____ mg **(Max 3.8mg dose per vial)**

**SrCr:** _____ **(For renal impairment [CrCl <50ml/min] dose must be reduced by 50%)**

**Recommended Dosage:**

**Maximum approval for adults: 0.05mg/kg once daily**

**Maximum approval for pediatric patients ≥ 10kg: 0.05mg/kg dose once daily**

**CLINICAL CRITERIA:** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

**Initial Approval Length - 6 months.** (All information must be noted or submitted with request form.)

**(Continued on next page)**

- ❑ Member has been dependent on parenteral nutrition/intravenous fluids (PN/IV) therapy **≥ 3 times per week** for **≥ 12 continuous months and failed previous trials of weaning (attach supportive documentation demonstrating the requirement of parenteral support)**
  - Frequency of current PN/IV use: _____ /week
  - Baseline of volume: _____ L/week or per infusion
  - Member's Body Mass Index (BMI): _____ $kg/m^2$

**AND**

- ❑ Member must have diagnosis of short bowel syndrome

**OR**

- ❑ Short bowel syndrome due to Crohn's disease with documentation of clinical remission of Crohn's disease **(attach supportive documentation demonstrating the clinical remission of Crohn's disease)**

**AND**

❑ Member received a colonoscopy or alternate imaging with removal of polyps **(if necessary)** within **six (6) months** prior to initiation of therapy

Date of colonoscopy **(must be within 6 months)**: _____

## EXCLUSIONS:

- Age <1 year old **OR** ≤ 10 kg
- Diagnosis of active cancer within the last 5 years
- Body Mass Index (BMI) is <15 $kg/m^2$
- Member received human growth hormone (e.g. Zorbtive) within the last 6 months
- Member has had four or more SBS-related hospital admissions within the last 12 months
- Member has an active intestinal obstruction

**First Continuation of Therapy - 6 months.** (All lines below must be completed)

- Has member had at least 20% reduction from baseline in parenteral nutrition/intravenous fluid (PN/IV)? ❑ YES ❑ NO
- Frequency of current PN/IV use: _____ /week
- Six (6) months from baseline: _____ L/week or per infusion **(supportive documentation must be attached)**
- Member's Body Mass Index (BMI): _____ $kg/m^2$
- Member does not have any FDA labeled contraindications to therapy: ❑ YES ❑ NO
- Labs must be submitted every six (6) months and colonoscopy one (1) year after initiation of therapy **(supportive documentation must be attached)**

**(Continued on next page)**

**Second Continuation of Therapy - 1 year after initial approval: 6 months.** (All lines below need to be completed)

- Has member had at least 20% reduction from last parenteral nutrition/intravenous fluid (PN/IV)? ❑ YES ❑ NO
- Frequency of current PN/IV use: _____ /week
- Volume: _____ L/week or per infusion **(supportive documentation must be attached)**
- Member's Body Mass Index (BMI): _____ $kg/m^2$
  - Member does not have any FDA-labeled contraindications to therapy: ❑ YES ❑ NO
  - Labs must be submitted every 6 months and colonoscopy one 1 year after initiation of therapy and then every 5 years after **(supportive documentation must be attached)**

**Continuation of Therapy - > 1.5 years after initial approval: 6 months.** (All lines below need to be completed)

- Has member's use of parenteral nutrition/intravenous fluid (PN/IV) stabilized and not increased from last baseline six (6) months ago? **(If NO is checked, it will be denied)** ❑ YES ❑ NO
- Frequency of current PN/IV use: _____ /week
- Volume: _____ L/week or per infusion **(supportive documentation must be attached)**
- Member's Body Mass Index (BMI): _____ $kg/m^2$
- Member does not have any FDA-labeled contraindications to therapy: ❑ YES ❑ NO
- Labs must be submitted **every 6 months** and **colonoscopy 1 year after initiation of therapy** and then **every 5 years after (supportive documentation must be attached)**

**Medication being provided by Specialty Pharmacy - PropriumRx**

***Not all drugs may be covered under every Plan***

***If a drug is non-formulary on a Plan, documentation of medical necessity will be required.***

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pha rmacy paid claims or submitted chart notes.****



***Approved by Pharmacy and Therapeutics Committee**: 11//20/2014
**REVISED/UPDATED/REFORMATTED:** ~~1/26/2015; 5/21/2015; 12/27/2015; 12/16/2016; 8/13/2017; 3/31/2018;10/14/2019;~~ **10/27/2023**