Gattex® (Teduglutide [rDNA origin]) for Injection

OnePath® Start Form: Authorization for OnePath Services

Phone: 1-866-888-0660 Fax: 1-855-359-3393

Available for patients 18 years of age and older.

ONEPATH

1 Prescribing Physician Information

Name (First, Last) | Site Name

Street Address | City | State | Zip Code

( ) Telephone | ( ) Fax | Office Contact

Tax ID # | State License # | National Provider ID #

2 Patient Information

Name (First, Middle Initial, Last) | ☐ Male ☐ Female | DOB: Month/Day/Year | Age | Last 4 digits of SSN

Street Address | City | State | Zip Code

( ) Home Telephone | ( ) Mobile Telephone | ( ) Work Telephone | E-mail Address

Caregiver Name (First, Last) | Relationship to Patient | ( ) Caregiver Telephone

3 Insurance Information

Please attach copies of both sides of patient's insurance card(s) ☐ **Check if patient does not have insurance**

Primary Insurance | ( ) Insurance Telephone

Policy ID # | Group # | Policy Holder Name (First, Last) and Relationship to Patient

Pharmacy Plan Name | ( ) Pharmacy Telephone

Policy ID # | Group # | Rx Bin # | Rx PCN #

Secondary Insurance | ( ) Insurance Telephone

Policy ID # | Group # | Policy Holder Name (First, Last) and Relationship to Patient

4 Diagnosis

☐ **Short Bowel Syndrome (SBS)**

☐ **New Patient:** Dependent on parenteral support? ☐ **Yes** ☐ **No**

☐ **Existing Patient:** GATTEX renewal

5 Additional Information

Date of last resection:

Parenteral support provider:

6 GATTEX *Prescription and Prescribing Physician Signature*

Prescription: GATTEX® (Teduglutide [rDNA origin]) for Injection **30-Vial Kit NDC # 68875-0102-1** **Vial Size: 5 mg** **ICD-10:**

Dose: 0.05 mg/kg/day ☐ Reduce dose by 50%: patient has moderate or severe renal impairment (creatinine clearance <50 mL/min), or end-stage renal disease.

Patient weight: _____ **kg** **Patient dose:** _____ (Patient weight) **kg × 0.05 =** _____ **mg/day** **Volume:** _____ (Patient weight) **kg ÷ 200 =** _____ **mL/day**

☐ My patient requires a home nurse visit for training on proper self-administration of GATTEX.

Number of refills: _____ Special Precautions (e.g. allergies):

I appoint Shire Human Genetic Therapies, Inc., its affiliates and their representatives (collectively "Shire") to convey on my behalf the prescription described herein to a pharmacy, if applicable.

Prescriber Signature (stamps not acceptable): DISPENSE AS WRITTEN Date:

7 *Patient Authorization to Share Personal Health Information*

I authorize any health plan, physician, health care professional, hospital, clinic, pharmacy provider or other health care provider (collectively, "Health Care Providers") to disclose my personal health information, including information relating to my medical condition, treatment, care management, and health insurance, as well as all information provided on this form and any prescription, personal health information obtained by Health Care Providers prior to the date of this authorization ("Personal Health Information"), to Shire Human Genetic Therapies, Inc., its affiliates and their representatives, agents, and contractors (collectively, "Shire") and to receive financial remuneration from Shire in exchange, for the following purposes: for Shire to provide product support services, including coordination of benefits and therapy; reimbursement support; investigating insurance coverage; communicating with me by mail, email, or telephone about my medical condition, treatment, care management, and health insurance; and internal use by Shire, including data analysis. I understand that my Personal Health Information disclosed under this authorization may be re-disclosed by Shire and no longer protected by federal privacy laws. I understand, however, that Shire agrees to undertake reasonable efforts to maintain my Personal Health Information in a secure manner and not to disclose it to third parties without a legitimate reason for doing so. I understand that I may refuse to sign this Authorization and that my treatment, payment, enrollment or eligibility for benefits, including my access to therapy, is not conditioned on my signing this Authorization. I understand that I am entitled to a signed copy of this Authorization. This Authorization expires one year from the date of execution, or one year after the date of my last prescription, whichever is later. I understand that I may revoke this Authorization at any time by sending written notice of revocation to OnePath®, 300 Shire Way, Lexington, MA 02421, which becomes effective upon receipt by any Health Care Provider subject to federal privacy laws, except to the extent that action already has been taken in reliance on this Authorization.

Patient Signature: Date:

(if applicable) Guardian/Legal Representative Signature: Date:

8 *Patient Authorization for Shire's OnePath Services*

I certify that all of the information provided on this form is complete and accurate. I authorize Shire to collect Personal Health Information from me, my caregivers, and Health Care Providers, and to use and disclose such Personal Health Information to provide product support services, including but not limited to coordination of benefits and therapy; reimbursement support; investigating insurance coverage; communicating with me by mail, email, or telephone about my medical condition, treatment, care management, and health insurance.

Patient Signature: Date:

(if applicable) Guardian/Legal Representative Signature: Date:

ADDITIONAL GUIDANCE FOR COMPLETION OF FORM

1 Prescribing Physician Information

- Fill out completely

2 Patient Information and 3 Insurance Information

- Do not submit to Shire any documentation of labs, clinical history, or other documents supporting the prior authorization process
- OnePath services are available for patients 18 years of age and older. Limitations to OnePath services will apply as shown below

4 Diagnosis and 5 Additional Information

- The physician is **required** to confirm the diagnosis
- The safety and efficacy of GATTEX in pediatric patients have not been established

6 Prescription and Prescribing Physician Information

- The recommended daily dose of GATTEX is 0.05 mg/kg body weight administered by subcutaneous injection once daily. Alternation of sites for subcutaneous injection is recommended, and can include the thighs, arms, and the quadrants of the abdomen. GATTEX should **not** be administered intravenously or intramuscularly. If a dose is missed, that dose should be taken as soon as possible on that day. Do not take 2 doses on the same day
- Reduce the dose by 50% in patients with moderate and severe renal impairment (creatinine clearance <50 mL/min), and end-stage renal disease
- The efficacy and safety of GATTEX in pediatric patients have not been established
- This is a prescription; therefore, a physician's signature and date are required
- Limitations to OnePath services may apply, dependent upon patient type as shown in the table below

Short Bowel Syndrome (SBS) patient information	Example of services available to eligible patients through OnePath
New adult patient with SBS, dependent on parenteral support	• Benefits investigation • Injection training • Co-pay support (when applicable) and information about third-party financial assistance programs, as necessary • Enrollment in OnePath: Case Manager assignment and product support services
Existing adult patient with SBS on GATTEX, who is/was dependent on parenteral support	
Adult patient with SBS, not dependent on parenteral support	• Benefits investigation • Injection training • Information about third-party financial assistance programs as necessary • Referral to Specialty Pharmacy (SPP)
Additional limitation: Patients under 18 years of age	

Indication

- GATTEX® (Teduglutide [rDNA origin]) for Injection is indicated for the treatment of adult patients with Short Bowel Syndrome who are dependent on parenteral support
- GATTEX has been approved with a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of GATTEX outweigh the risks

Important Safety Information

- **Warnings and Precautions:** Possible acceleration of neoplastic growth and enhanced growth of colon polyps, gastrointestinal obstruction, gallbladder, biliary tract and pancreatic disease, increased absorption of fluids leading to fluid overload, especially in patients with underlying cardiovascular disease, and increased absorption of oral medications requiring titration or with a narrow therapeutic index
- The most common adverse reactions (≥10%) across all studies with GATTEX are abdominal pain, injection site reactions, nausea, headaches, abdominal distension, and upper respiratory tract infection. In addition, vomiting and fluid overload were reported in the Short Bowel Studies (1 and 3) at rates ≥10%
- Across all clinical trials (595 patients), 21.8% of patients experienced an injection-site reaction

Please click here to see the full Prescribing Information.

7 Patient Authorization to Share Personal Health Information

- The patient signature is required to allow personal health information to be shared by third parties to Shire to facilitate access to GATTEX (insurance benefits, self-administration training, transfer Rx to SPP, etc)

8 Patient Authorization for Shire OnePath Services

- The patient signature allows eligible patients to receive product support services to assist them in obtaining GATTEX

What Happens Next?

- Once the completed form has been submitted to OnePath, a dedicated Case Manager will be assigned to eligible patients and will contact those patients directly to inform them of the process and all services that may be available to them through OnePath
- The Case Manager will determine insurance benefits and, if applicable, OnePath will assess the patient's eligibility for co-pay support and other means to allow the patient to access GATTEX