Gattex® (Teduglutide [rDNA origin]) for Injection

OnePath® Start Form: Authorization for OnePath® Services

Fax this completed form to: 1-855-359-3393 Phone: 1-866-888-0660

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 _____ E-mail Address _____

Street Address _____ City _____ State _____ Zip Code _____

Home Telephone (____) _____ Mobile Telephone (____) _____ Work Telephone (____) _____

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, Etiology, and GATTEX® Prescription

Diagnosis*

☐ **New Start: Short Bowel Syndrome (SBS) patient dependent on parenteral nutrition and/or IV fluids (parenteral support)**

☐ **Existing Patient: GATTEX® renewal**

***Please do not check a box if neither apply.**

Etiology

☐ **Acute Events (ie, Vascular Event, Trauma, Intestinal Obstruction)**

☐ **Chronic Conditions (ie, IBD, Crohn's Disease)**

☐ **Congenital Anomaly**

Date of last intestinal resection: _____ Parenteral Nutrition Provider/Pharmacy: _____

PRESCRIPTION

GATTEX® (Teduglutide [rDNA origin]) for Injection

30-Vial Kit NDC # 68875-0102-1

Vial Size: 5 mg **ICD Code:** _____ **Dose: 0.05 mg/kg/day**

Patient weight: _____ **kg**

Patient dose: _____ (Patient weight) **kg × 0.05 =** _____ **mg/day**

Volume: _____ (Patient weight) **kg ÷ 200 =** _____ **mL/day**

☐ **Reduce dose by 50%: Patient has moderate to severe renal impairment (creatinine clearance <50mL/min, or end-stage renal disease).** Adjusted patient dose _____ mg/day Adjusted volume _____ mL/day

Number of refills: _____

Special Precautions (eg, allergies): _____

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

Sign here

Prescriber Signature: _____ DISPENSE AS WRITTEN **Date:** _____

(stamps not acceptable)

5 Patient Authorization to Share Personal Health Information and OnePath® Enrollment

☑ 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 redisclosed 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.

☐ ***OnePath® Enrollment*** (must check box to be enrolled in product support services through OnePath®)

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.**

Sign here

Patient Signature: _____ Date: _____

Legal Representative Signature **(if applicable)**: _____ 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, Etiology, and GATTEX® Prescription

- The physician is **required** to select the box corresponding to the patient's diagnosis. The diagnosis section should only be left blank if neither apply
- The safety and efficacy of GATTEX® in pediatric patients have not been established
- 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
- Check the box if your patient has renal impairment. Reduce the dose by 50% in patients with moderate and severe renal impairment (creatinine clearance <50 mL/min), and end-stage renal disease
- 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®
Adult SBS patient dependent on parenteral nutrition and/or IV fluids (parenteral support)	• Benefits investigation • Injection training • Co-pay assistance (when applicable) and information about financial assistance options, as necessary • Enrollment in OnePath®: Dedicated Patient Support Manager and personalized product support services
Other diagnosis	• Benefits investigation • Injection training • Referral to Specialty Pharmacy (SPP)
Additional limitation: Patient 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, and increased absorption of oral medications
- 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 SBS Studies (1 and 3) at rates ≥10%
- Across all clinical trials (595 patients), 21.8% of patients experienced an injection-site reaction

Please see full Prescribing Information provided by the Shire representative.

5 Patient Authorization to Share Personal Health Information and OnePath® Enrollment

- 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)
- The OnePath® Enrollment checkbox is required to allow eligible patients to receive product support services to assist them in obtaining GATTEX®
- If the patient's healthcare proxy is signing on the patient's behalf as legal representative, please submit the legal documentation of healthcare proxy with the START form or as soon as possible

What Happens Next?

- Once the completed form has been submitted to OnePath®, a dedicated Patient Support Manager will be assigned to eligible patients and will contact those patients directly to inform them of the services that may be available to them through OnePath® to help them gain access to their prescribed treatment
- The Patient Support Manager will facilitate insurance benefits verification and, if applicable, OnePath® will assess the patient's eligibility for co-pay assistance and other means to allow the patient to access GATTEX®

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Shire