

**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**

**Rx** **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: \_\_\_\_\_ kg × 0.05 = \_\_\_\_\_ mg/day  
 Patient weight

Volume: \_\_\_\_\_ kg ÷ 200 = \_\_\_\_\_ mL/day  
 Patient weight

**Reduce dose by 50%: Patient has moderate to severe 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)	<ul style="list-style-type: none"> <li>• Enrollment in OnePath®: Dedicated Patient Support Manager and personalized product support services</li> <li>• Benefits investigation</li> <li>• Injection training</li> <li>• Co-pay assistance (when applicable) and information about financial assistance options, as necessary</li> </ul>
Other diagnosis	<ul style="list-style-type: none"> <li>• Benefits investigation</li> <li>• Injection training</li> </ul>
Additional limitation: Patient under 18 years of age	<ul style="list-style-type: none"> <li>• Referral to Specialty Pharmacy (SPP)</li> </ul>

## 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 at [http://www.shirecontent.com/PI/PDFS/Gattex\\_USA\\_ENG.pdf](http://www.shirecontent.com/PI/PDFS/Gattex_USA_ENG.pdf).

## 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®

Please fax this completed form to: 1-855-359-3393



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