OnePath® Start Form: Authorization for OnePath® Services

Available for patients 1 year of age and older

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

1. PRESCRIBING PHYSICIAN INFORMATION

Name (First, Last) | Treatment Center

Street Address | City

State | Zip Code | Telephone | Fax

Office Contact Name | Office Contact Email

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

2. PATIENT INFORMATION

Name (First, Middle Initial, Last) ☐ Male ☐ Female

DOB: MM/DD/YYYY | Last 4 Digits of SSN | Email

Street Address | City | State | Zip Code

Primary Telephone | Secondary Telephone | Special Precautions (eg, allergies)

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

***Optional** *HCP Care Team Member (First, Last)* | *Telephone*

By providing the name(s) of my other Care Team Member(s) above (health care providers other than the GATTEX prescribing physician), I am authorizing any employees of the Company (as defined on page 2) to follow up with these Care Team Member(s) to provide education and information about GATTEX.

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) | Relationship to Patient | Date of Birth

Pharmacy Plan Name | Pharmacy Telephone

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

Secondary Insurance | Insurance Telephone | Policy ID # | Group #

Policy Holder Name (First, Last) | 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**
(eg, vascular event, trauma, intestinal obstruction)

☐ **Chronic Conditions**
(eg, IBD, Crohn's disease)

☐ **Congenital Anomaly**
(eg, gastroschisis, midgut volvulus)

Date of Last Intestinal Resection | Parenteral Support Provider/Pharmacy

Rx

PRESCRIPTION

GATTEX® (teduglutide) for injection | ICD-10 Code

☐ **Dose: 0.05 mg/kg once daily**

5 mg kit is not recommended in patients weighing less than 10 kg

Patient weight (kg) x 0.05 (dose (mg)) = Patient dose (mg/day)

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

☐ **Reduce dose to 0.025 mg/kg once daily:** Patient has moderate or severe renal impairment or end-stage renal disease (estimated glomerular filtration rate (eGFR) less than 60 mL/min/1.73 m^2)

Patient weight (kg) x 0.025 (dose (mg)) = Patient dose (mg/day)

Patient weight (kg) ÷ 400 = Volume (mL/day)

Dispense:

☐ **One (1) 30-Vial Kit NDC # 68875-0102-1 Vial Size: 5 mg**
(Maximum obtained from 1 vial after reconstitution is 3.8 mg)

☐ **Two (2) 30-Vial Kits NDC # 68875-0102-1 Vial Size: 5 mg**

Directions:
Administer _____mg (_____mL) dose subcutaneously, under the skin, once daily.

Number of refills

I appoint Takeda, its affiliates and their representatives to convey on my behalf the prescription described herein to a pharmacy, if applicable.

Prescriber Signature
(stamps not acceptable, dispense as written)

Date

OnePath®

Gattex® (teduglutide) for injection

Authorization for OnePath® Services (cont'd)

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5. PATIENT OR LEGAL GUARDIAN AUTHORIZATION TO SHARE PROTECTED HEALTH INFORMATION

☑ I authorize any health plan, physician, health care professional, hospital, clinic, pharmacy provider or other health care provider (collectively, "Providers") to disclose my, or my child's (as applicable), protected health information, including personal information relating to my, or my child's, medical condition, treatment, care management, and health insurance, as well as all information provided on this form and any prescription ("Information"), to Shire Human Genetic Therapies, Inc., its affiliates and their representatives, agents, and contractors (collectively, the "Company") in connection with the Company's provision of products, supplies, or services. I understand the Company will provide this Information to a pharmacy within the GATTEX specialty pharmacy network. This Information may also be used for internal uses by the Company, including data analysis.

Further, the Company may use this Information for OnePath Product Support Services (if I opt-in below) such as verification of insurance benefits and drug coverage, prior authorization support, financial assistance with co-pays, patient assistance programs, alternate funding sources, other related programs, communication with me or my prescribing physician (or my child's) by mail, email, or telephone about my, or my child's, medical condition, treatment, care management, product information and health insurance.

Additionally, if I check the box below regarding marketing communications, I authorize the Company to use and disclose my, or my child's, Information to send marketing materials to me (as described below).

I understand that employees of the Company only see my, or my child's, Information in connection with administering the OnePath Product Support Program, or in connection with other activities referenced herein, or as otherwise required or allowed under the law. I understand that they will make every effort to keep my, or my child's, Information private, but if it is accidentally shared with an associated party, my, or my child's, Information disclosed under this Authorization may no longer be protected by federal privacy law. I understand that I am entitled to a copy of this Authorization. I understand that I may cancel this Authorization at any time by sending written notice of revocation to OnePath, 300 Shire Way, Lexington, MA 02421. I understand that such revocation will not apply to any Information already used or disclosed through this Authorization. This Authorization will expire within five (5) years from today's date, unless a shorter period is provided for by state law. I understand that I may refuse to sign this Authorization and that refusing to sign this Authorization will not change the way my, or my child's, physician, health insurance, and pharmacy providers treat me or my child. I also understand that if I do not sign this Authorization, I, or my child, will not be able to receive OnePath Product Support Program products, supplies, or services.

ONEPATH® ENROLLMENT (must check box below to be enrolled in product support services through OnePath®)

☐ I am electing to enroll in OnePath Product Support Services (which may include, but is not limited to, verification of insurance benefits and drug coverage, prior authorization support, financial assistance with co-pays, patient assistance programs, alternate funding sources, other related programs, communication with me or my prescribing physician (or my child's) by mail, email, or telephone about my, or my child's, medical condition, treatment, care management, product information and health insurance).

Patient/Legal Representative Signature	Date	Patient Name	Legal Representative Name and Relationship

PATIENT CONSENT FOR FUTURE INFORMATION

☐ By checking this box, I consent to receiving marketing and promotional communications from the Company. I hereby give consent to the Company to send communications and information to me via the contact information I have provided above. I understand that this consent will be in effect until such time as I opt-out of communications from the Company.

OnePath® Gattex® (teduglutide) for injection

Additional Guidance for Completion of Form

Fax this completed form to: 1-855-359-3393

1. PRESCRIBING PHYSICIAN INFORMATION

- **Fill out completely**
- Any attached documents will not be forwarded to the dispensing pharmacy

2. PATIENT INFORMATION AND 3. INSURANCE INFORMATION

- Do not submit to the Company any documentation of labs, clinical history, or other documents supporting the prior authorization process
- OnePath® services are available for patients 1 year of age and older and/or their caregivers, as applicable. Limitations to OnePath® services will apply

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 under 1 year of age 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
- GATTEX® is for adult self-administration or caregiver administration. Self-administration in pediatric patients has not been tested. Use of the GATTEX 5 mg kit is not recommended in pediatric patients weighing less than 10 kg
- Check the box if your patient has renal impairment. The recommended dosage in adult and pediatric patients with moderate and severe renal impairment and end-stage renal disease (estimated glomerular filtration rate (eGFR) less than 60 mL/min/1.73 m^2) is 0.025 mg/kg once daily
- This is a prescription; therefore, a physician's signature and date are required

5. PATIENT AUTHORIZATION TO SHARE PERSONAL HEALTH INFORMATION AND ONEPATH® ENROLLMENT

- The patient or legal guardian signature is required to allow Information (as defined on page 2) to be shared by third parties to the Company to facilitate access to GATTEX® (insurance benefits, administration training, transfer Rx to SPP, etc)
- The OnePath® Enrollment checkbox is required to allow eligible patients and/or caregivers 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 completed 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/or caregivers and will contact them directly to inform them of the services that may be available to them through OnePath® to help them gain access to the 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®

Indication

- GATTEX® (teduglutide) for injection is 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.
- 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:** GATTEX® has been associated with acceleration of neoplastic growth, intestinal obstruction, biliary and pancreatic disease, fluid imbalance and fluid overload, and increased absorption of concomitant oral medication.
- The most common adverse reactions (≥10%) with GATTEX® are abdominal pain, nausea, upper respiratory tract infection, abdominal distension, injection site reaction, vomiting, fluid overload, and hypersensitivity.
- **Use in Specific Populations:** Breastfeeding is not recommended during treatment with GATTEX®.

Please click here for full Prescribing Information.