Gattex®
(teduglutide) for injection

SUPPORT FOR GETTING PATIENTS STARTED WITH GATTEX®

This resource contains:

- ☑ The OnePath® Start Form
- ☑ Guidance for Prescribers
- ☑ Guidance for Patients

Your **Takeda representative** is available to answer any additional questions.

For more information about OnePath, please call **1-866-888-0660**, Monday through Friday, 8:30 AM to 8:00 PM eastern time, or visit **OnePath.com**

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.

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.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

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STARTING PATIENTS ON GATTEX®

STEP 1 Complete the GATTEX Risk Evaluation and Mitigation Strategy (REMS) Program

- The purpose of GATTEX REMS is to inform healthcare providers and patients about the following risks:
  - Acceleration of neoplastic growth and enhancement of colon polyp growth
  - Gastrointestinal obstruction
  - Biliary and pancreatic disorders
- Please review the REMS education materials and complete the knowledge assessment at www.gattexrems.com. REMS materials are also available through your GATTEX representative

STEP 2 Counsel your patient

- Please share the appropriate REMS materials with your patients, including:
  - The Medication Guide prior to starting therapy, ensuring they fully understand the risks and benefits of GATTEX
  - The Patient & Caregiver Counseling Guide to review during each visit
  - Both resources are available at www.gattexrems.com
- Please ensure the patient has filled out their section of the **OnePath® Start Form**, reviewed the patient authorizations, and signed the Start Form
- After they have signed the Start Form, give your patient the *Guidance for Patients* resource in this document to provide more information about available OnePath support for patients on GATTEX
  - Please be sure to fill out the Patient Support Manager (PSM) and Onboarding & Access Specialist (OAS) contact information provided by your Regional Business Manager (RBM) prior to giving it to the patient

STEP 3 Submit the OnePath Start Form with signed patient consent

- The Start Form serves as the prescription for GATTEX and enrolls your patient in OnePath
  - OnePath provides product support services to eligible patients prescribed GATTEX, including arranging specialty pharmacy ordering and providing a dedicated PSM, OAS, and Nurse Educator. Refer to the Guidance for Patients resource in this document for more information
- Please fill out the insurance and prescribing physician information, diagnosis, etiology, and prescription sections completely.* **Incomplete forms may cause delays in treatment initiation**
  - Confirm the patient or caregiver has completed the patient information section of the Start Form and that they've read the OnePath authorization and consent information
  - **Both patient and prescriber signatures are required to authorize this form.** If your patient is unable to come to the office to sign the form, OnePath can obtain their consent via alternate methods. If you have any questions about the consent process, please contact your Takeda representative
- OnePath Start Forms are available at startgattex.com, from your Takeda representative, or by calling **1-866-888-0660**
  - Fax the completed Start Forms to **1-855-359-3393**
  - Please be aware that the Start Form is **not** an insurance prior authorization form

STEP 4 Perform safety assessments within 6 months prior to starting GATTEX treatment*

In adult patients

- Perform a colonoscopy of the entire colon with removal of polyps
- Obtain baseline laboratory assessments (bilirubin, alkaline phosphatase, lipase, and amylase)

In children and adolescents ≥1 year of age

- Perform fecal occult blood testing; if there is unexplained blood in the stool, perform colonoscopy/sigmoidoscopy
- Obtain baseline laboratory assessments (bilirubin, alkaline phosphatase, lipase, and amylase)

- Additional information on monitoring timelines is available in the educational brochure provided by your Takeda representative, online at www.gattexhcp.com/resources/, and in the Full Prescribing Information

*Do not submit any documentation of labs, clinical history, or other documents supporting the prior authorization process. Any attached documents will not be forwarded to the dispensing pharmacy.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

GUIDANCE FOR PATIENTS

NEXT STEPS TO GETTING STARTED ON GATTEX®

The **OnePath®** Product Support Program offers personalized assistance throughout your treatment journey

Now that you've decided to start treatment with GATTEX, completed the Start Form, and elected to enroll in the OnePath Product Support Program, please refer to the checklist below to see what you can expect next.

☐ Your OnePath team includes your dedicated **Patient Support Manager (PSM)**. Upon enrollment, your PSM will call you to:

- Explain OnePath services and obtain your consent
- Confirm the information on your Start Form, including insurance benefits and coverage

Your PSM welcome call may last around 30 minutes. ***Please be sure to have your insurance information available.***

Your PSM (Name, Phone) _____

☐ Your OnePath team also includes your **Onboarding & Access Specialist (OAS)**. Your OAS will set up a meeting to help you get started with treatment and answer any questions related to:

- Insurance and financial assistance options
- GATTEX and potential side effects
- Next steps in your treatment journey

Your OAS (Name, Phone) _____

☐ Once your insurance company approves your GATTEX prescription, it will be sent to you by a **specialty pharmacy** (a mail-order pharmacy that provides specialty medications)

- Your specialty pharmacy will reach out to confirm delivery and can also guide and support you in administering your treatment

☐ A **Nurse Educator** (ie, GATTEX Injection Training Nurse) will come to your home and train you on how to administer GATTEX according to the Instructions for Use

- The Nurse Educator can meet with you up to 4 times to ensure that you know how to administer GATTEX
- Please contact your OAS or PSM for ongoing support

Note: Depending on your insurance, the timeline for starting GATTEX can vary. To avoid delays, **please be sure to answer calls** from your OnePath support team, specialty pharmacy, and Nurse Educator, which may come from unknown numbers.

Call OnePath at 1-866-888-0660, Monday through Friday, 8:30 AM to 8:00 PM eastern time, or visit www.gattex.com/getting-started/ to learn more.

Please discuss any questions with your doctor.

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Gattex® (teduglutide) for injection

BOTH PATIENT AND PRESCRIBER SIGNATURES ARE REQUIRED TO AUTHORIZE THIS FORM.

OnePath® Start Form: Authorization for Services

Available for patients 1 year of age and older

OnePath Gattex (teduglutide) for injection

FAX PAGE 1 OF THIS FORM TO: 1-855-359-3393
PHONE: 1-866-888-0660

TO BE COMPLETED BY PATIENT

1. PATIENT INFORMATION

Full Name _____

DOB (MM/DD/YYYY) _____ ☐ Male ☐ Female

Last 4 Digits of SSN _____ Email _____

Address _____

City/State/ZIP _____

Primary Phone _____ Secondary Phone _____

Special Precautions (eg, allergies) _____

Caregiver (First, Last) _____

Relationship to Patient _____ Phone _____

By providing the names of my other Care Team Members on this form (healthcare providers other than the GATTEX prescribing physician), I am authorizing any employees of the Companies to follow up with these Care Team Members to provide education and information about GATTEX.

HCP Care Team Member* (First, Last) _____

Care Team Role _____ Phone _____

☐ Español es mi primer idioma

*Optional.

☐ I would like to opt in to marketing communications

Patient Authorization

I have read, understand, and agree to the release of my protected health information, as described on Page 2, Section 6 of this form.

X _____ _____

Patient signature/legal representative signature (indicate relationship) DATE

OnePath Patient Support Program and Communications Enrollment

I have read, understand, and agree to the use of my personal information for the purposes described on Page 2, Section 7 of this form.

X _____ _____

Patient signature/legal representative signature (indicate relationship) DATE

2. INSURANCE INFORMATION

REQUIRED: Include copies of both sides of the patient's medical and prescription insurance card(s) ☐ Check if the patient does not have insurance

Primary Insurance _____ Insurance Phone _____

Policy ID # _____ Group _____

Policy Holder Name (First, Last) _____

DOB (MM/DD/YYYY) _____ Relationship to Patient _____

Secondary Insurance _____ Insurance Phone _____

Policy ID # _____ Group _____

Policy Holder Name (First, Last) _____

DOB (MM/DD/YYYY) _____ Relationship to Patient _____

Pharmacy Plan _____ Policy ID # _____ Group # _____

Pharmacy Plan Phone _____ Rx Bin # _____ Rx PCN # _____

TO BE COMPLETED BY OFFICE/PHYSICIAN

3. PRESCRIBING PHYSICIAN INFORMATION

Full Name _____ Treatment Center _____

Address _____

City/State/ZIP _____

Phone _____ Fax _____

Office/Clinic Name _____ Office Contact Name _____

Office Contact Phone _____ Office Contact Email _____

National Provider ID _____

4. PATIENT CLINICAL INFORMATION

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 applies.**

Date of Last Intestinal Resection _____

ICD-10 Code _____

Etiology

☐ **Inflammatory Bowel Disease (IBD)**
(eg, chronic conditions such as Crohn's disease)

☐ **Non-IBD**
(eg, acute events [vascular event, trauma, intestinal obstruction], congenital anomaly [gastroschisis, midgut volvulus])

Parenteral Support Provider/Pharmacy _____

5. PRESCRIPTION FOR GATTEX (teduglutide) FOR INJECTION

The prescriber must comply with state specific prescription requirements such as state specific prescription form, e-prescribing, etc.

STEP 1: Calculate patient dosage (check one box below)

☐ **Dose: 0.05 mg/kg once daily** (5 mg kit is not recommended in patients weighing less than 10 kg)

☐ **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 m²)

Complete both calculations

_____ (patient weight (kg)) × _____ (Multiply by 0.05 **OR** 0.025 per above) = _____ (patient dose (mg/day))

_____ (patient weight (kg)) ÷ _____ (Divide by 200 (0.05 dose) **OR** 400 (0.025 dose)) = _____ (volume (mL/day))

STEP 2: Choose # of 30-vial kits needed

If dose is more than 3.8 mg/day, two 30-vial kits are recommended†

☐ **One (1) 30-Vial Kit**/NDC # 68875-0102-01/Vial Size: 5 mg
†A maximum of 0.38 mL of the reconstituted solution, containing 3.8 mg of teduglutide, can be withdrawn from the vial for dosing.

☐ **Two (2) 30-Vial Kits**/NDC # 68875-0102-01/Vial Size: 5 mg

STEP 3: Enter directions

Administer _____ mg (_____ mL) dose subcutaneously, under the skin, once daily. Number of refills _____

By signing this form, I certify that therapy with GATTEX is medically necessary for the patient identified in this application ("Patient"). I have reviewed the current GATTEX Prescribing Information and will be supervising Patient's treatment. I have received from Patient, or his/her personal representative, the necessary authorization to release, in accordance with applicable federal and state law regulations, referenced medical and/or other patient information relating to GATTEX therapy to Takeda Pharmaceuticals U.S.A., Inc., including its agents or contractors (the "Company"), for the purpose of seeking information related to coverage and/or assisting in initiating or continuing GATTEX therapy. I authorize OnePath to transmit this prescription to a pharmacy within the GATTEX specialty pharmacy network. I agree that product provided shall only be used for Patient. I understand that I am under no obligation to prescribe or purchase GATTEX or any other product manufactured by the Company, and I certify I have received nothing of value from the Company or its agents or representatives for prescribing a Company product.

X _____ _____

Prescriber Signature (Stamps not acceptable; dispense as written) DATE

X _____ _____

Prescriber Signature (Substitution permitted) DATE

Authorization for OnePath Services

PLEASE READ THROUGH THE LANGUAGE ON THIS PAGE BEFORE SIGNING THE AUTHORIZATION AND CONSENT IN SECTION 1 OF THE START FORM.

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

By signing the Patient Authorization section of the Start Form, I authorize any health plan, physician, healthcare professional, hospital, clinic, pharmacy provider or other healthcare 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 Takeda Pharmaceuticals U.S.A., 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. I understand that Providers may receive financial remuneration from Company for marketing services.

Further, the Company may use this Information for OnePath Product Support Services 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.

I understand that employees of the Company only see my, or my child's, Personal Health 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 they will make every effort to keep my, or my child's Information private, but once my, or my child's, Personal Health Information is disclosed under this Authorization, it may no longer be protected by federal privacy law and subject to re-disclosure. 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.

7. ONEPATH AND COMMUNICATIONS ENROLLMENT

By signing the OnePath Patient Support Program and Communication Enrollment section on the first page of this Start Form, 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).

By checking the box on Page 1 labeled "I would like to opt in to marketing communications," I consent to receiving marketing and promotional communications from Takeda. I hereby give consent to Takeda, its affiliates, and their agents and representatives 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 Takeda.

I understand that I may revoke my permission at any time. To learn how Takeda will use and protect my personal information, please review our Privacy Policy (www.takeda.com/en-us/privacy-policy).

Please click here for full Prescribing Information.

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IMPORTANT INFORMATION

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.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Acceleration of neoplastic growth

Colorectal polyps were identified during clinical trials. There is a risk for acceleration of neoplastic growth. In adults, within 6 months prior to starting treatment with GATTEX, colonoscopy of the entire colon with removal of polyps should be performed and follow-up colonoscopy (or alternate imaging) is recommended at the end of 1 year of GATTEX. Subsequent colonoscopies should be performed every 5 years or more often as needed.

In children and adolescents, perform fecal occult blood testing prior to initiating treatment with GATTEX. Colonoscopy/sigmoidoscopy is required if there is unexplained blood in the stool. Perform subsequent fecal occult blood testing annually in children and adolescents while they are receiving GATTEX. Colonoscopy/sigmoidoscopy is recommended for all children and adolescents after 1 year of treatment, every 5 years thereafter while on continuous treatment with GATTEX, and if they have new or unexplained gastrointestinal bleeding.

In case of intestinal malignancy (GI tract, hepatobiliary, pancreatic), discontinue GATTEX. The clinical decision to continue GATTEX in patients with non-gastrointestinal malignancy should be made based on benefit-risk considerations.

Intestinal obstruction

Intestinal obstruction has been reported in clinical trials and postmarketing. In patients who develop intestinal or stomal obstruction, GATTEX should be temporarily discontinued pending further clinical evaluation and management.

Biliary and pancreatic disease

Cholecystitis, cholangitis, cholelithiasis, and pancreatitis have been reported in clinical trials and postmarketing. Laboratory assessment (bilirubin, alkaline phosphatase, lipase, amylase) should be obtained within 6 months prior to starting GATTEX. Subsequent laboratory tests should be done every 6 months or more often as needed. If clinically meaningful changes are seen, further evaluation is recommended including imaging, and continued treatment with GATTEX should be reassessed.

Fluid imbalance and fluid overload

Fluid overload and congestive heart failure have been observed in clinical trials. If fluid overload occurs, especially in patients with underlying cardiovascular disease, parenteral support should be adjusted and GATTEX treatment reassessed. If significant cardiac deterioration develops while on GATTEX, continued GATTEX treatment should be reassessed.

Discontinuation of treatment with GATTEX may also result in fluid and electrolyte imbalance. Fluid and electrolyte status should be monitored in patients who discontinue treatment with GATTEX.

Increased absorption of concomitant oral medication

In clinical trials, one patient receiving prazepam concomitantly with GATTEX experienced dramatic deterioration in mental status progressing to coma during first week of GATTEX therapy. Patients receiving concomitant oral drugs requiring titration or with a narrow therapeutic index should be monitored for adverse reactions due to potential increased absorption of the concomitant drug. The concomitant drug may require a reduction in dosage.

Adverse Reactions

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.

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