Steps to starting patients on GATTEX®

Indication
GATTEX (teduglutide [rDNA origin]) for injection is indicated for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

Warning and Precautions
GATTEX has been associated with 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.

Please see Important Safety Information on page 7 and click for full Prescribing Information and Medication Guide.
Step 1: What you will need to do first

Complete GATTEX REMS Program
- The purpose of the GATTEX® REMS is to inform healthcare providers and patients about the following risks:
  - Possible acceleration of neoplastic growth and enhancement of colon polyp growth
  - Gastrointestinal obstruction
  - Biliary and pancreatic disorders
- Prescribers who intend to treat patients with GATTEX should review the education materials which are part of the REMS, available at www.gattexrems.com or through your GATTEX representative
- Prescribers should also complete the knowledge assessment

Counsel the patient
Prior to treatment, patients should fully understand the risks and benefits of GATTEX
- Ensure that all patients receive the Medication Guide prior to initiating GATTEX therapy
- Review the Patient & Caregiver Counseling Guide with your patient each time and provide your patient with a copy to take home
- Both resources are available at www.gattexrems.com

Submit the OnePath® Start Form with signed patient consent
- The Start Form serves as the prescription and allows OnePath to facilitate insurance benefits investigation, Specialty Pharmacy ordering, and injection training for eligible patients
- OnePath Start Forms are available at www.gattex.com/hcp, through your GATTEX representative, or by calling 1-866-888-0660

Initial safety monitoring
- Within 6 months prior to starting treatment on GATTEX, perform the following safety assessments:

<table>
<thead>
<tr>
<th>Laboratory Assessments</th>
<th>Description</th>
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<tbody>
<tr>
<td>Colonoscopy (or alternate imaging)</td>
<td>Examine the entire colon with removal of polyps</td>
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<tr>
<td>Bilirubin</td>
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<tr>
<td>Alkaline phosphatase</td>
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<tr>
<td>Lipase</td>
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<tr>
<td>Amylase</td>
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Step 2: OnePath can help eligible patients prescribed GATTEx®*

- A Patient Support Manager will contact your patients to:
  - Facilitate benefits verification
  - Connect them with a OnePath Onboarding and Access Specialist, Specialty Pharmacy and Nurse Educator

- Onboarding and Access Specialists are local resources for product support. An Onboarding and Access Specialist will:
  - Work closely with your patients during the first few months
  - Provide educational information about GATTEX for your patients to discuss with you
  - Provide information about financial assistance options, if needed
  - Answer questions your patients may have about the steps to getting GATTEX as prescribed

- Meet with an Onboarding and Access Specialist

- The Specialty Pharmacy will:
  - Contact patients to discuss GATTEX and any required co-pays
  - Arrange delivery of GATTEX to the patient’s home

- Arrange for a Specialty Pharmacy

- The Nurse Educator will:
  - Schedule an in-home injection training visit
  - Instruct patients and caregivers on how to prepare, mix and administer GATTEX (up to four weekly training visits)
  - Remind patients they can call a nurse 24/7 with any questions about mixing, administration and storage of GATTEX

- Schedule a Nurse Educator visit

*Eligibility criteria and limitations of services may apply.

Please see Important Safety Information on page 7 and click for full Prescribing Information and Medication Guide.
Step 3: Monitor to assess safety in patients continuing on GATTEX®

<table>
<thead>
<tr>
<th></th>
<th>Ongoing</th>
<th>Every 6 months</th>
<th>After 1 year of GATTEX</th>
<th>At least every 5 years</th>
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<tbody>
<tr>
<td><strong>Colonoscopy</strong>&lt;br&gt;(or alternate imaging)</td>
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<tr>
<td>Amylase</td>
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<tr>
<td><strong>Clinical Evaluations</strong></td>
<td></td>
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<tr>
<td>Signs and symptoms of fluid overload</td>
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<td>x</td>
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<tr>
<td>Increased absorption of concomitant medication(s)</td>
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<td></td>
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<tr>
<td>Signs and symptoms of intestinal obstruction</td>
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<tr>
<td>Observation of other adverse reactions</td>
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Discontinuation of treatment with GATTEX may result in fluid and electrolyte imbalance. Therefore, patients’ fluid and electrolyte status should be carefully monitored.
Frequently Asked Questions

Q: How much does OnePath cost?
A: OnePath product support services are free of charge.

Q: How long does it take from the time I complete the OnePath Start Form until the patient begins treatment with GATTEX®?
A: The length of time can vary and is dependent on a number of factors including the patient’s insurance, injection training and medication delivery.

Q: What if my patient’s healthcare insurance changes?
A: Patients should contact their OnePath Patient Support Manager for help in understanding their new insurance coverage benefits and possible financial assistance options.

Q: What resources can OnePath provide to my patients?
A: OnePath offers a patient portal and OnePath Mobile App to allow patients to contact their Patient Support Manager. In addition, the OnePath Mobile App provides patients with a customized SBS eDiary to track their health.

Important Contact Information

Shire Area Business Specialist name: ________________________________

Phone number: ________________________________________________

OnePath Patient Support Manager name: ____________________________

Phone number: ________________________________________________

OnePath Onboarding and Access Specialist name: ____________________

Phone number: ________________________________________________

Other: _________________________________________________________

______________________________________________________________

______________________________________________________________

Please see Important Safety Information on page 7 and click for full Prescribing Information and Medication Guide.
Talking with patients about their treatment goals

It is important for patients to keep their treatment goals in mind throughout the process of getting them started on GATTEX® (Teduglutide [rDNA origin]) for Injection.

It may be helpful for patients to write down their reasons for beginning treatment and the importance of monitoring and follow-up.

At OnePath, We’re Here to Help

OnePath is committed to providing product support to all eligible adult patients who have been prescribed GATTEX.

1-866-888-0660
www.OnePath.com

Need more information about OnePath or patient eligibility criteria?

Call us at 1-866-888-0660, Monday through Friday, 8:30AM to 8:00PM ET
Indication

GATTEX® (teduglutide [rDNA origin]) for Injection is indicated for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

Important Safety Information

Warnings and Precautions

**Neoplastic growth**
Colorectal polyps were identified during clinical trials. There is a risk for acceleration of neoplastic growth. Colonoscopy of the entire colon with removal of polyps should be done within 6 months prior to starting treatment with GATTEX and is recommended after 1 year. Subsequent colonoscopies should be done as needed, but no less frequently than every 5 years. 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 risk and benefit considerations.

**Intestinal obstruction**
Intestinal obstruction has been reported in clinical trials. In patients who develop 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. Patients should undergo laboratory assessment (bilirubin, alkaline phosphatase, lipase, amylase) before starting GATTEX. Subsequent laboratory tests should be done every 6 months. If clinically meaningful changes are seen, further evaluation is recommended including imaging, and continued treatment with GATTEX should be reassessed.

**Fluid overload**
Fluid overload and congestive heart failure have been observed in clinical trials. There is potential for fluid overload while on GATTEX. If fluid overload occurs, especially in patients with underlying cardiovascular disease, parenteral support should be appropriately adjusted and GATTEX treatment reassessed.

**Increased absorption of concomitant oral medication**
Altered mental status in association with GATTEX has been observed in patients on benzodiazepines in clinical trials. Patients on concomitant oral drugs (e.g., benzodiazepines, phenothiazines) requiring titration or with a narrow therapeutic index may require dose adjustment while on GATTEX.

Adverse Reactions

The most common adverse reactions (≥10%) across all studies with GATTEX are abdominal pain, injection site reactions, nausea, headaches, abdominal distension, upper respiratory tract infection. In addition, vomiting and fluid overload were reported in the SBS studies (1 and 3) at rates ≥10%.

To report suspected adverse events, please contact Shire at 1-866-888-0660 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please click for full Prescribing Information and Medication Guide.