Indication
GATTEX (teduglutide) 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
GATTEX has been associated with possible acceleration of neoplastic growth, intestinal obstruction, biliary and pancreatic disease, fluid imbalance and fluid overload, and increased absorption of concomitant oral medication.

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

- 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](http://www.gattexrems.com) or through your GATTEX representative
- Prescribers should also complete the knowledge assessment

Complete GATTEX REMS Program

Counsel the patient

- 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](http://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](http://www.gattex.com/hcp), through your GATTEX representative, or by calling 1-866-888-0660

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

<table>
<thead>
<tr>
<th>Initial safety monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Colonoscopy</strong> (or alternate imaging)</td>
</tr>
<tr>
<td>- Bilirubin</td>
</tr>
<tr>
<td>- Alkaline phosphatase</td>
</tr>
<tr>
<td>- Lipase</td>
</tr>
<tr>
<td>- Amylase</td>
</tr>
</tbody>
</table>

Please see Important Safety Information on page 7 and click here for full Prescribing Information.
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

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

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

*Eligibility criteria and limitations of services may apply.

Provide a dedicated Patient Support Manager

Meet with an Onboarding and Access Specialist

Arrange for a Specialty Pharmacy

Schedule a Nurse Educator visit

Please see Important Safety Information on page 7 and click here for full Prescribing Information.
## 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>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Colonoscopy</strong> (or alternate imaging)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Examine the entire colon with removal of polyps</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>Laboratory Assessments</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bilirubin</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Alkaline phosphatase</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Lipase</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Amylase</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>Clinical Evaluations</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Signs and symptoms of intestinal or stomal obstruction</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Signs and symptoms of fluid imbalance and fluid overload</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Increased absorption of concomitant oral medication(s)</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Observation of other adverse reactions</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

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.
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 here for full Prescribing Information.
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) 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, 8:30 AM to 8:00 PM ET
Indication
GATTEX® (teduglutide) 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

Acceleration of neoplastic growth
Colorectal polyps were identified during clinical trials. There is a risk for acceleration of neoplastic growth. Within 6 months prior to starting treatment with GATTEX, colonoscopy (or alternate imaging) 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 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.
For more information about getting patients started on GATTEX®, contact your GATTEX® representative or call Shire at 1-866-888-0660.

Please click here for full Prescribing Information.