FOR HEALTHCARE PROVIDERS

A Guide for Patient Expectation Management and Weaning Parenteral Support

Educational resources to help navigate your patients through their short bowel syndrome (SBS) treatment journey

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

Intestinal polyps were identified during clinical trials. Postmarketing cases of colorectal, gastric, and small intestinal (duodenum, ileum, and jejunum) polyps have been reported. There is a risk for acceleration of neoplastic growth. In adults, within 6 months prior to starting treatment with GATTEX, perform colonoscopy and an upper gastrointestinal (GI) endoscopy with removal of polyps. A follow-up colonoscopy and upper GI endoscopy (or alternate imaging) is recommended at the end of 1 year of GATTEX. Subsequent colonoscopies and upper GI endoscopies (or alternate imaging) should be performed every 5 years or more often as needed. If a polyp is found, adherence to current polyp follow-up guidelines is recommended.

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Reducing Dependence on Parenteral Support Is an Important Goal

Reducing or eliminating parenteral support (PS) are important treatment goals for any patient with SBS. Establishing these goals will require a discussion of symptom management, treatment expectations, and diet/lifestyle modifications. Focusing on potential benefits may help patients better understand their treatment and long-term goals, so within you will find data, patient characteristics, weaning guidance, and resources to help your patients better understand their treatment.[1,2]

Parenteral support can be lifesaving for patients with SBS, however long-term use of PS may lead to other complications, such as[3-8]*:

Hepatobiliary Diseases
ie, intestinal failure-associated liver disease [IFALD] and gallstones

Kidney Diseases
ie, hyperoxaluria

Central Venous Complications
ie, septic infections, thrombosis and loss of vascular access

Metabolic Bone Disease
ie, osteoporosis

Parenteral support can be intravenous fluids and/or nutrition.[2]

*The effects of GATTEX® (teduglutide) on these complications were not studied.[9]

IMPORTANT SAFETY INFORMATION (Cont'd)

Warnings and Precautions (Cont'd)

Acceleration of Neoplastic growth (Cont'd)

In pediatric patients, perform fecal occult blood testing within 6 months prior to initiating treatment with GATTEX. If there is new or unexplained blood in the stool, perform colonoscopy/sigmoidoscopy and an upper GI endoscopy. Perform subsequent fecal occult blood testing annually in pediatric patients while they are receiving GATTEX, followed by colonoscopy/sigmoidoscopy and an upper GI endoscopy if there is new or unexplained blood in the stool. Colonoscopy/sigmoidoscopy is recommended for all pediatric patients after 1 year of treatment and at least every 5 years thereafter while on continuous treatment with GATTEX. Consider upper GI endoscopy (or alternate imaging) during treatment with GATTEX.

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Patient Characteristics that Positively Impact Weaning

Develop a weaning plan based on patient characteristics, as well as a patient's treatment goals

Patients with SBS differ in age and pathophysiology, as well as in duration of PS and nutritional status. These and other factors can impact weaning. It may be important to consider a wide range of characteristics that may contribute to a better chance for your patients reducing PS.[1,6]

Patient characteristics that can positively impact a PS weaning plan[1,10]

Length of remnant bowel	Length of remnant bowel is important and can increase chances of weaning success
Presence of a colon	Provides better chance of PS weaning by facilitating fluid and energy absorption
Presence of ileum/ileocecal valve	Slows small bowel transit time and may reduce reflux of colonic bacteria into the small intestine
Sufficient bowel adaption	Increases absorption and extends intestinal transit time
Absence of underlying pathology/disease	Patients free of underlying conditions (ie, Crohn's disease, radiation enteritis, carcinoma) generally experience more complete PS weaning
Compliance	Patient compliance with all therapies (diet, oral rehydration solutions [ORS], antidiarrheal, other medications) can impact weaning success
Oral intake	The ability to tolerate oral intake can be a factor in facilitating the PS weaning process

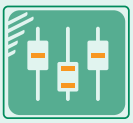
Weaning PS Is a Multistep Process

Setting the proper expectations for your patients weaning PS is essential. It is important for patients to understand that reducing PS is a multistep process that will take time. Outlining your plan for patients may help them adhere to their treatment. The four-step breakdown is: **Prepare, Optimize, Modify, Monitor**.[1,2]

Prepare[1,2]

ESTABLISH WITH PATIENT

- ✓ Treatment goals
- ✓ Symptom management
- ✓ Diet/lifestyle adjustments
- ✓ Indicators of dehydration and the benefits of oral rehydration solutions
- ✓ Multidisciplinary team members (MDT)



Optimize[1,2]

BEGIN ADJUSTING

- ✓ PS & oral fluid intake
- ✓ Medication for SBS symptom management (ie, antidiarrheal, antisecretory, pain management)
- ✓ Customize diet & ORS

Expectation Management & Goal-setting

Weaning PS is a process and will be different for each patient. While achieving enteral autonomy may not be possible for everyone, patients should understand reducing volume and/or time spent on PS are also key goals.[1,2]

Next Steps to Start Weaning PS

Continue to modify and monitor your patient's nutrition, renal function, and weight, aiming to optimize and prepare for PS reduction, if possible.

Modify[1,2]

ONCE OPTIMIZED

- ✓ Reduce PS volume or frequency (hours or days off)
- ✓ Modify hydration/nutrition (if necessary)
- ✓ Adjust SBS symptom medications (if needed)
- ✓ Evaluate renal function
- ✓ Correct for any deficiencies (electrolyte, nutrient, vitamin)
- ✓ Ensure increasing oral fluid intake with ORS

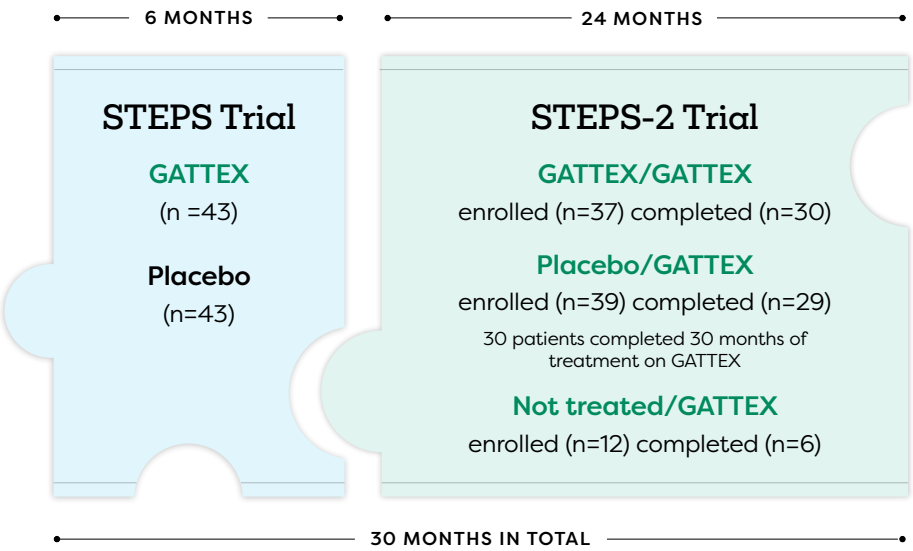
Monitor[1,2]

ESTABLISH WITH PATIENT

- ✓ Electrolytes, mineral and vitamin supplements
- ✓ Renal function
- ✓ Goals, reassess as needed
- ✓ Compliance with diet, ORS, and supplements
- ✓ Weight
- ✓ Laboratory assessments*

*See specific labs on page 13.

GATTEX Pivotal Studies[9]



Primary endpoint:
Defined as a ≥20% reduction in weekly PS volume from baseline (ie, immediately before randomization to Weeks 20 and 24 in STEPS and start of GATTEX treatment to the last visit in STEPS-2)

Patient baseline characteristics in STEPS (average, range)[9,11]:

Age (50 years, 18-82 years); Estimated small bowel length (77.3 cm; 5-343 cm); Length of time on PS (6 years, 1-26 years); Prescribed days per week on PS (5.73 days; 3-7 days); Infusion volume (13 L/week; 0.9-35 L/week).

Patients had varying types of intestinal resection[9]

- 44% (37/85) of patients did not have a colon in continuity; an average of 37% of the colons in these patients had been removed
- 54% (13/24) of patients with an intact distal/terminal ileum had an ileocecal valve
- Stoma (most commonly jejunostomy and ileostomy) was present in 45% (38/85) of patients

IMPORTANT SAFETY INFORMATION (Cont'd)

Warnings and Precautions (Cont'd)

Acceleration of Neoplastic growth (Cont'd)

In adult and pediatric patients who develop active gastrointestinal 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.

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FOR PATIENTS ≥1 YEAR OF AGE WITH SHORT BOWEL SYNDROME (SBS) WHO ARE DEPENDENT ON PARENTERAL SUPPORT (PS)

GATTEX Is an FDA-Approved Analog of Naturally Occurring GLP-2[9]

In clinical studies of patients with SBS, GATTEX was proven to[9]:

Significantly* reduce weekly parenteral support (PS) VOLUME requirements

Help patients achieve MORE TIME OFF parenteral support

Help some patients achieve ENTERAL AUTONOMY from parenteral support

In a 6-month study, adult patients treated with GATTEX reduced weekly PS volume by ≥20% (27/43) vs placebo (13/43) and achieved a reduction of ≥1 day off PS per week (21/39) vs placebo (9/39).
In a 24-month open-label extension, adult patients previously treated with GATTEX weaned off PS completely after 30 months of treatment (10/30).[9]
In a 6-month study, pediatric patients treated with GATTEX reduced weekly PS volume by ≥20% (18/26), achieved a reduction of ≥1 day off PS per week (10/26), and weaned off PS completely (3/26).[9]

Most common adverse reactions (≥5% in GATTEX group vs greater than in the placebo group)[9]

Abdominal pain (**30%** vs 22%)†, nausea (**23%** vs 20%), upper respiratory tract infections (**21%** vs 12%)‡, abdominal distension (**20%** vs 2%), injection site reaction (**13%** vs 12%)§, vomiting (**12%** vs 10%), fluid overload (**12%** vs 7%)¶, hypersensitivity (**10%** vs 7%)‖, flatulence (**9%** vs 7%), decreased appetite (**7%** vs 3%), influenza (**7%** vs 2%)#, skin hemorrhage (**5%** vs 2%)**, cough (**5%** vs 0%), and sleep disturbances (**5%** vs 0%)††.

- If patients have a stoma, advise them that, while they may experience abdominal pain and swelling of their stoma, especially when starting treatment with GATTEX, if they experience symptoms of intestinal obstruction, they should contact their physician[9]
- Among the 53 patients with a stoma in the placebo-controlled studies, the percentage of patients with gastrointestinal stoma complication was 42% (13/31) for patients who received GATTEX 0.05 mg/kg/day and 14% (3/22) for patients who received placebo[9]

GLP-2, glucagon-like peptide-2.
*See Study Design above.
†Includes: Abdominal pain, upper abdominal pain, lower abdominal pain.[9]
‡Includes: Upper respiratory tract infection, nasopharyngitis, pharyngitis, sinusitis, laryngitis, rhinitis, viral upper respiratory tract infection.[9]
§Includes: Injection site hematoma, injection site erythema, injection site pain, injection site swelling, injection site hemorrhage, injection site discoloration, injection site reaction, injection site rash.[9]
¶Includes: Fluid overload, peripheral edema, edema, generalized edema, fluid retention, and jugular vein distension.[9]
‖Includes: Erythema, rash, dermatitis allergic, pruritus, rash macular, drug eruption, eyelid edema, flushing.[9]
#Includes: Influenza, influenza-like illness.[9]
**Includes: Hematoma, abdominal wall hematoma, post-procedural hematoma, umbilical hematoma, blood blister.[9]
††Includes: Insomnia (3 patients) and hypersomnia (1 patient).[9]

IMPORTANT SAFETY INFORMATION (Cont'd)

Warnings and Precautions (Cont'd)

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.

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Time to Response & Residual Anatomy: Early and Late Responders

A Takeda-sponsored post-hoc analysis of STEPS and STEPS-2 identified factors that may be associated with mean time to sustain PS reduction.[12]*

Early Responders[12]

3.6 Months

(n=27) (1.1 SD)

Adult patients who completed STEPS with a PS volume reduction of ≥20% from baseline at both Week-20 and Week-24 visits during STEPS.

Late Responders[12]

10.0 Months

(n=7) (6.1 SD)

Adult patients who completed STEPS-2 and had a PS volume reduction of ≥20% from baseline at any 2 consecutive visits during the extension study or at both the Week-24 visit in STEPS and the Month-1 visit in STEPS-2.

- PS volume reduction was defined as 2 consecutive visits with a PS volume reduction of ≥20%[12]
- Time to sustained PS volume reduction was defined as the period between the baseline visit for STEPS and the second consecutive visit at which PS volume reduction was ≥20%[12]
- This is a post-hoc analysis of patients who completed STEPS and STEPS-2. Please note that efficacy in STEPS was based on the intent-to-treat population, while efficacy in STEPS-2 was based on study completers. Further randomized, controlled clinical studies are necessary to corroborate these findings.[12]

SD, standard deviation.

*To evaluate factors associated with sustained PS volume reduction and early vs late response, a Takeda-sponsored post-hoc analysis was conducted for patients with SBS who were treated with GATTEX in the STEPS study (n=43) and who then continued treatment with GATTEX for up to 24 months in the extension study, STEPS-2.[12]

IMPORTANT SAFETY INFORMATION (Cont'd)

Warnings and Precautions (Cont'd)

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.

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Anatomy Remaining per Response

Residual bowel anatomy influenced time to response[12]

PATIENT ANATOMY REMAINING

Early Responders[12]

- **Lower percentage** had **colon-in-continuity** (51.9%)
- Patients had a **lower mean percentage** of **colon remaining** (24.6%)
- **Fewer** patients had an **ileocecal valve** (0%)

Late Responders[12]

- **Higher percentage** had **colon-in-continuity** (100%)
- Patients had a **higher mean percentage** of **colon remaining** (57.1%)
- **More** patients had an **ileocecal valve** (28.6%)

Discuss treatment expectations

Time to response may vary for each patient. Ongoing discussion on response time with your patient is important.[12]

Study limitations: This study was limited by the relatively small sample size, which may not have sufficient statistical power to identify factors associated with response. This study was also limited by the heterogeneity within the group of patients who had SBS with intestinal failure. The population consisted of patients who were subject to specific inclusion and exclusion criteria. Thus, the results may have limited generalizability.[12]*

A Kaplan-Meier analysis was conducted for time to sustained PS volume reduction; a multivariable Cox proportional hazards model was used for predictors of sustained PS volume reduction. Time to sustained PS volume reduction was described for early and late responders. Patient characteristics were described and compared between early vs late responders using chi-square tests for categorical variables and Wilcoxon rank sum tests for continuous variables.[12]

IMPORTANT SAFETY INFORMATION (Cont'd)

Warnings and Precautions (Cont'd)

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.

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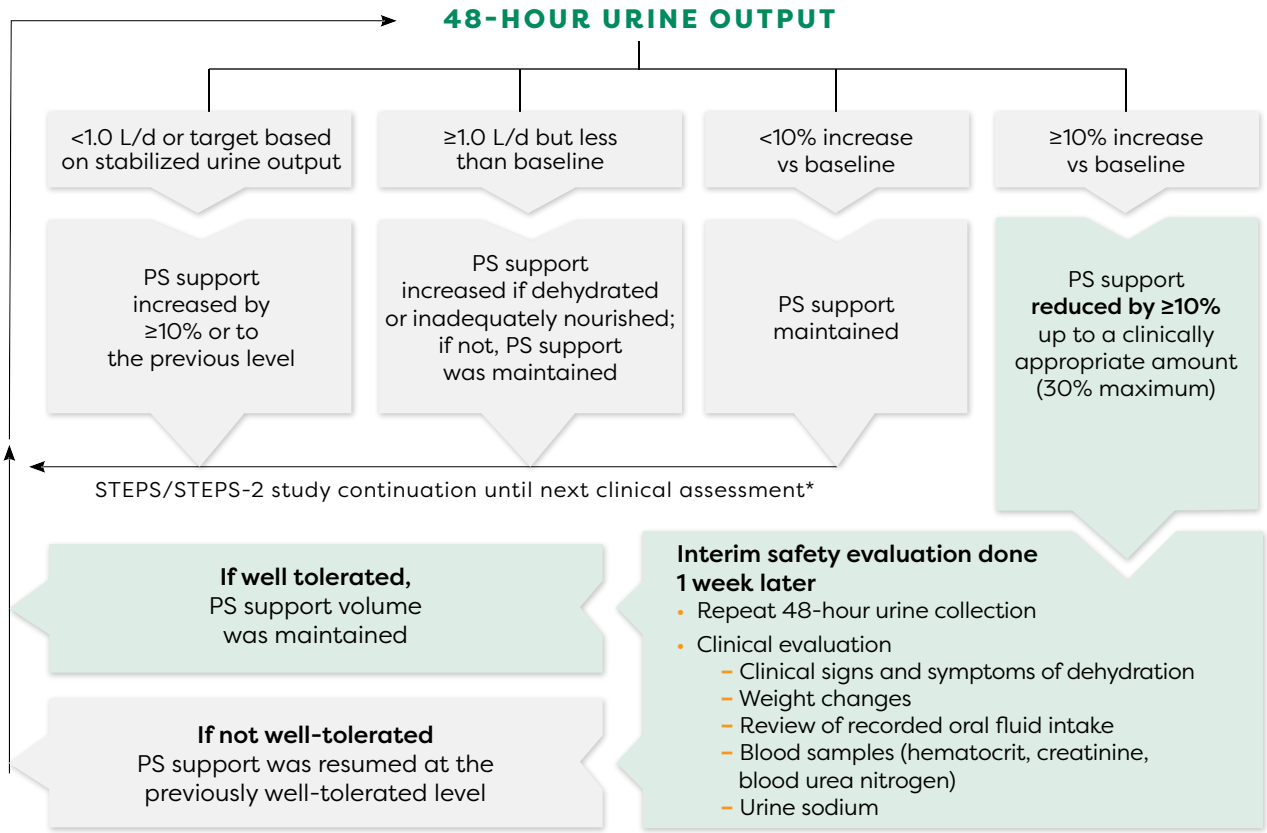
Weaning Protocol from STEPS and STEPS[11,13]

Modification to PS & monitoring



PS support reductions were spread across all days.

*Baseline urine output is the urine volume obtained during the stabilization period before initiating treatment.[11,13]

IMPORTANT SAFETY INFORMATION (Cont'd)

Warnings and Precautions (Cont'd)

Fluid imbalance and fluid overload (Cont'd)

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.

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Infusion Reduction in STEPS and STEPS-2[11,13]

Optimized and stable

In STEPS and STEPS-2 studies, once a patient was optimized and stable, PS infusions were slowly reduced over time. Gradual reductions minimize the risk of dehydration and increase the likelihood of weaning success. Reductions in PS are often made in one of the following ways[1,2,11,13]:

- Total infusion volume per week
- Number of infusion days per week
- Infusion volume per day
- Number of infusion hours per day

STEPS and STEPS-2 measured urine output, but alternative approaches are available[1,14]

Nutrition-focused Physical Assessment

Stool Output

Oral Intake

Electrolyte and Micronutrient Levels

Body Weight

IMPORTANT SAFETY INFORMATION (Cont'd)

Warnings and Precautions (Cont'd)

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.

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Building a PS Weaning Plan

Evaluate weaning in terms of intake, output, and other clinical measures–consider[1,2]:

- A patient's intake (oral, enteral and parenteral support)
- A patient's output (stool, urine, ostomy, etc)
- Regular body weight monitoring
- Hydration tracked through urine output
- Lab testing to confirm nutritional needs are met

Multidisciplinary care may improve outcomes in weaning PS[2,15]

Engaging a team across disciplines can improve outcomes, reduce complications, and give patients the support they need when trying to achieve enteral autonomy.

- Surgeon
- Gastroenterologist
- Dietitian
- Pharmacist
- Primary care physician
- Advanced practice provider
- Social worker
- Home care company
- Specialty pharmacist
- Ostomy nurse

IMPORTANT SAFETY INFORMATION (Cont'd)

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.

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Ongoing Monitoring

Parameters monitored in STEPS[16,17]

(Evaluated every 1-4 weeks)

- Glucose, BUN, creatinine, electrolytes, calcium, magnesium, phosphorous
- CBC with differential
- Total bilirubin, direct bilirubin, AP, AST, ALT
- PTT, PT, INR
- Triglyceride level
- Serum proteins (total protein and albumin)
- Cholesterol
- GGT
- LDH
- Complete urinalysis

Additional parameters to consider monitoring in clinical practice[17]

Included in ASPEN Consensus Recommendations for monitoring during parenteral nutrition

Iron indices
Zinc, selenium, manganese, copper, chromium
Vitamin A, 25-OH vitamin D, vitamin E
Vitamin B12 and folate
Carnitine
TSH

If a patient cannot maintain adequate hydration or nutrition status after full PS weaning, PS should be restarted.

ALT, alanine aminotransferase; AP, alkaline phosphatase; AST, aspartate aminotransferase; BUN, blood urea nitrogen; CBC, complete blood count; GGT, gamma-glutamyl transferase; INR, international normalized ratio; LDH, lactate dehydrogenase; PT, prothrombin time; PTT, partial thromboplastin time; TSH, thyroid-stimulating hormone.

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Warnings and Precautions (Cont'd)

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References: 1. DiBaise JK, Matarese LE, Messing B, Steiger E. *J Clin Gastroenterol.* 2006;40(Suppl 2):S94-S98. **2.** Ukleja A. *Gastroenterol Clin North Am.* 2019;48(4):525-550. **3.** Vipperla K, O'Keefe SJ. *Expert Rev Gastroenterol Hepatol.* 2011;5(6):665-678. **4.** Jeppesen PB, Gilroy R, Pertkiewicz M, et al. *Gut.* 2011;60(7):902-914. **5.** Buchman AL. Short Bowel Syndrome. In: Feldman M, Friedman L, Brandt L. *Sleisenger and Fordtran's Gastrointestinal and Liver Disease. Pathophysiology, Diagnosis, Management.* 10th ed. 2015;1832-1848. **6.** Hofstetter S, Stern L, Willet J. *Curr Med Res Opin.* 2013;29(5):495-504. **7.** Mullady DK, O'Keefe SJ. *Nat Clin Pract Gastroenterol Hepatol.* 2006;3(9):492-504. **8.** Jeppesen PB. *JPEN J Parenter Enteral Nutr.* 2014;38(Suppl1):8S-13S. **9.** GATTEX (teduglutide) for injection [package insert]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc. **10.** Parrish CR. *A Patient's Guide to Managing a Short Bowel.* 5th ed. Carol Rees Parrish, MS, RD; 2021. **11.** Jeppesen PB, Pertkiewicz M, Messing B, et al. *Gastroenterology.* 2012;143(6):1473-1481. **12.** Chen K, Joly F, Mu F, et al. *Clin Nutr ESPEN.* 2021;43:420-427. **13.** Schwartz LK, O'Keefe SJ, Fujioka K, et al. *Clin Transl Gastroenterol.* 2016;7:e142. **14.** August D, Teitelbaum D, Albina J, et al. *JPEN J Parenter Enteral Nutr.* 2002;26(Suppl1): 1SA-138SA. **15.** Stanger JD, Oliveira C, Blackmore C, Avitzur Y, Wales PW. *J Pediatr Surg.* 2013;48(5):983-992. **16.** Data on file, Takeda Pharmaceuticals, Inc. **17.** Worthington P, Balint J, Bechtold M, et al. When is parenteral nutrition appropriate? *JPEN J Parenter Enteral Nutr.* 2017;41(3):324-377.

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Takeda Patient Support

Tailored Support for Your Patients Prescribed GATTEX

When you prescribe GATTEX for your patients,
Takeda Patient Support is here to support them and their caregivers.
Our support specialists provide several services, including:

Benefits investigation to help determine your patient's insurance benefits and eligibility for certain services, to help reduce time to access therapy

Prior authorization (PA), reauthorization, and appeals education in coordination with your patient's insurance company to determine any requirements

A review of financial assistance options for your patients

Specialty pharmacy triage and coordination*

Our support specialists are never more than a tap or a call away—**1-866-888-0660**, Monday through Friday, 8:30 AM to 8 PM ET.

Need to enroll your patient?
Visit our convenient online enrollment portal at TakedaPatientSupport.com/hcp.
You can also enroll your patient by faxing the completed Start Form to **1-855-268-1826**.

If English is not your patient's preferred language, we may be able to assist them in a language of their choosing.

*If your patient's medication is dispensed by a specialty pharmacy.

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Takeda

With nearly 30 years of experience in gastroenterology, Takeda continues its commitment to GI patients

Gattex® (teduglutide) for injection