FOR HEALTHCARE PROVIDERS

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

WEANING PARENTERAL SUPPORT WHILE ON GATTEX: AN EDUCATIONAL RESOURCE

Once you have decided GATTEX is appropriate for your patient, it's important to understand the weaning process. This resource provides information on weaning parenteral support (PS), which ranges from IV hydration to total parenteral nutrition (TPN), for patients with SBS. Not every patient will be able to wean completely off of PS. However, reducing the volume or number of days on PS may help patients reach their treatment goals.[1]

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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WEANING PS IS AN IMPORTANT GOAL FOR PATIENTS WITH SBS

Parenteral support (PS) can be lifesaving for patients with short bowel syndrome (SBS)[2]

When patients achieve and maintain nutrition/hydration goals with an optimal amount of PS (in conjunction with diet and antidiarrheals), there may be some hesitation to change therapy. However, once patients are optimized and stabilized on their individualized plan, they should begin reducing their dependence on PS.[2,3]

However, long-term use of PS should be minimized to avoid complications[4-6]

- Long-term PS is associated with numerous complications that can be serious and sometimes life-threatening, such as[7-9]*:
  - **Hepatobiliary diseases** (i.e. intestinal failure-associated liver disease [IFALD] and gallstones)
  - **Metabolic bone disease** (i.e. osteoporosis)
  - **Kidney diseases** (i.e. hyperoxaluria)
  - **Central venous complications** (i.e. septic infections, thrombosis, and loss of vascular access)

Use of PS may disrupt daily activities such as[4,8]:

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

WEANING PS IS A MULTISTEP PROCESS[2,3]

Preparation

- Establish treatment goals for PS reductions, symptom management, and diet/lifestyle modifications
- Educate patients about their condition and why it's important to reduce or eliminate PS
- Inform patients on the importance of their diet, signs of dehydration, and how oral rehydration solutions (ORS) can help
- Identify and coordinate with a multidisciplinary team (MDT)

Optimization

- Monitor hydration and nutrition status when adjusting PS and oral fluid intake
- Optimize medications used to treat SBS symptoms (ie, antidiarrheal, antisecretory, and pain management)
- Customize diet and use of ORS according to patient characteristics

PS modification and patient monitoring

- Once patient is optimized, begin reduction of PS volume or frequency (hours or days off)
- Monitor hydration and nutrition status at regular intervals
- Adjust medications for SBS symptoms if needed
- Monitor for electrolyte, nutrient, and vitamin deficiencies, as well as renal function
- Ensure the patient is increasing oral fluid intake with ORS

Ongoing monitoring

- Continue to monitor electrolytes as well as mineral and vitamin supplements at regular intervals, as needed
- Monitor renal function
- Reassess and establish new goals, as needed
- Observe patient compliance with diet, ORS, and supplements
- Monitor weight

Eliminating PS requirements is the ultimate goal for all patients with SBS, however reducing the hours per day or days per week on PS can provide substantial benefits.[1]

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.

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PREPARE A PERSONALIZED PS WEANING PLAN WITH YOUR PATIENTS

Develop the weaning plan based on patient characteristics as well as patients' treatment goals[3]

Patients with short bowel syndrome (SBS) differ in age and pathophysiology as well as in duration of parenteral support (PS) and nutritional status. These and other factors can impact weaning success.[2,8]

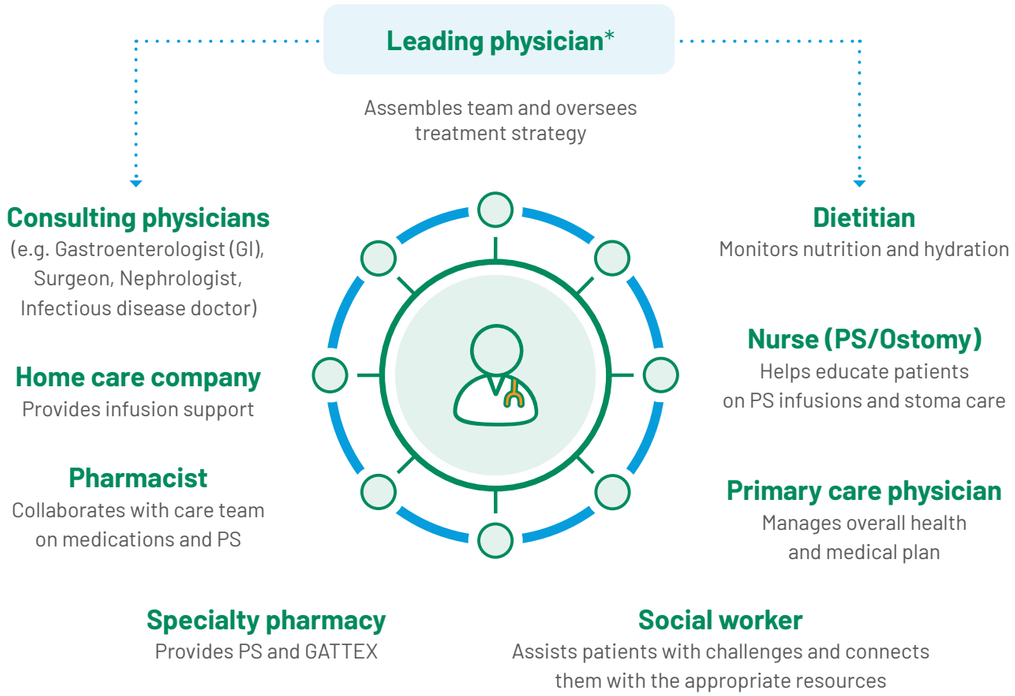
Patient characteristics that can positively impact a PS weaning plan[2,10]

Characteristic	Influence on weaning success
Length of remnant bowel	Length of remnant bowel is important and can increase chances of weaning success but ultimately function of bowel is the primary factor
Presence of a colon	Allows 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 adaptation	Increases absorption and extends intestinal transit time
Absence of underlying pathology/disease	Patients free of underlying conditions (i.e. 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

INCLUDE A MULTIDISCIPLINARY TEAM IN THE PS WEANING PLAN

A multidisciplinary team (MDT) can help ensure a successful weaning process[3,11-13]

Multidisciplinary care improves outcomes in weaning parenteral support (PS), facilitating enteral autonomy, and reducing complications. To establish an MDT, the first step is to start with a single dedicated physician who will drive the development of the team. This physician will connect with specialists needed to help support the patient. The size of the team may vary, depending on the circumstances. Start by adding a few specialists at a time who can contribute to the success of the patient's weaning goals.[3,11-13]



Coordinated care with strong communication among the MDT can help ensure the patient achieves their PS weaning goals.[3]

*While a Gastroenterologist is often the leading physician, other physicians could serve in this role as well.

IMPORTANT SAFETY INFORMATION

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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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PATIENT EDUCATION AND MOTIVATION ARE KEY TO SUCCESSFUL PS WEANING

A well-educated patient may feel more empowered to commit to a weaning plan[2,3,10]

It's important that patients actively participate throughout their journey and adhere to the weaning plan, which may include the following:

Monitoring urine output and providing blood and urine samples

Managing medications (antidiarrheal, antisecretory, pain management) and vitamin/mineral supplements

Recognizing signs and symptoms of dehydration and electrolyte imbalance

- Signs/symptoms may include: Thirst, fatigue, reduced urine and stoma output, dark urine, dry skin and dry mouth, lightheadedness

Modifying diet and monitoring nutrient and oral fluid intake based on regimen set by their HCP

- Increase oral intake of food to accommodate caloric goals
  - A high-carbohydrate, low-fat diet appears to be more useful for those with a colon-in-continuity
- Monitor oral fluid intake to ensure adequate hydration of ≥30 mL/kg/day
- Oral rehydration solutions are recommended to ensure proper hydration (approximately seven 8-oz glasses per day for a 54 kg [120 lb] person)
  - ORSs are particularly useful in patients without a colon

Water is not recommended for most patients with SBS.

Homemade Oral Rehydration Solution

1 quart of ready to drink Gatorade® G2 Low Calorie*
½ teaspoon salt

Directions: Add salt to ready to drink Gatorade G2 and shake well.

Note: Potassium levels in this recipe are well below the recommended amount for an ORS.

Find more ORS recipes

Important information for patients to know about short bowel syndrome (SBS) and parenteral support (PS) weaning[2,3]

Physiological changes associated with SBS	Explain the rationale behind the dietary changes, monitoring, and pharmacotherapies they will be taking
Setting treatment and personal goals	Everyone's experience will be different, so it's important to talk to the patient and set realistic goals that they can achieve
Expectations during the weaning process	• The weaning process is gradual and should be done over an extended period of time • Rapid PS discontinuation can put patients at a high risk for dehydration • Different interventions may be required on different days as the patient's needs may change

A stepwise, personalized weaning plan should accommodate the patient's unique needs[2,3]

Depending on patient characteristics, eliminating PS requirements may not be possible—**but patients may still achieve meaningful reductions in parenteral support (PS) volume and time, with fewer hours/days on PS**[1-3]

Clearly defined care protocols should be established for situations such as dehydration or nutritional instability that may require IV fluids or vitamin/mineral/electrolyte supplements and diet adjustment

Patients should have a good understanding of who is part of their multidisciplinary team, their contact information, and how each of them will help during the weaning process[3,11-13]

Patients need to remain consistent with all therapies
(modified diet, ORS, medications, vitamin/mineral/electrolyte supplements, and use of PS and adherence to PS reductions as directed)

Based on their characteristics, what are your patient's short- and long-term weaning goals? Is the end goal PS elimination, volume reduction, or reduced time on PS?

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*Gatorade® is a registered trademark of PepsiCo.

OPTIMIZATION PREPARES THE PATIENT FOR SUCCESSFUL PS WEANING

Optimizing hydration and nutrition prepares the patient for parenteral support (PS) reduction[2,3]

Patients should be nutritionally stable (ie, meet dry weight, steady calorie and protein intake from all sources) and well hydrated before they begin to wean PS. Therefore, it is recommended that steps be taken to optimize diet, oral fluid intake, and antidiarrheal/antisecretory/pain management medications before starting the weaning process to avoid dehydration and malnutrition.

- Daily fluid goal (targeting urine output >1 L/day) must be met to ensure adequate hydration
- Blood and urine samples can be used to evaluate hydration and nutrition

Other measures to consider when optimizing patients for PS weaning

- Daily caloric intake and weight should be steady before attempting PS weaning
- Patient should be clinically stable (ie, meet adequate electrolyte levels, fluid status and weight goal) before starting the weaning process

In the STEPS and STEPS-2 studies, PS/IV support was optimized and stabilized prior to randomization[14]

- For ≤8 weeks prior to randomization, investigators optimized the PN/IV volume of all patients
- Optimization was followed by a 4–8 week period of fluid stabilization

Criteria used to optimize and stabilize patients before initiating PS reduction in the STEPS study[15]

Optimization

- 48-hour measurements before each visit, included 1 day on and 1 day off of PS
  - Oral fluid intake
  - Urine output
- Urine output
  - Target: 1.0–2.0 L/d
  - PS was adjusted in increments of ≥10%

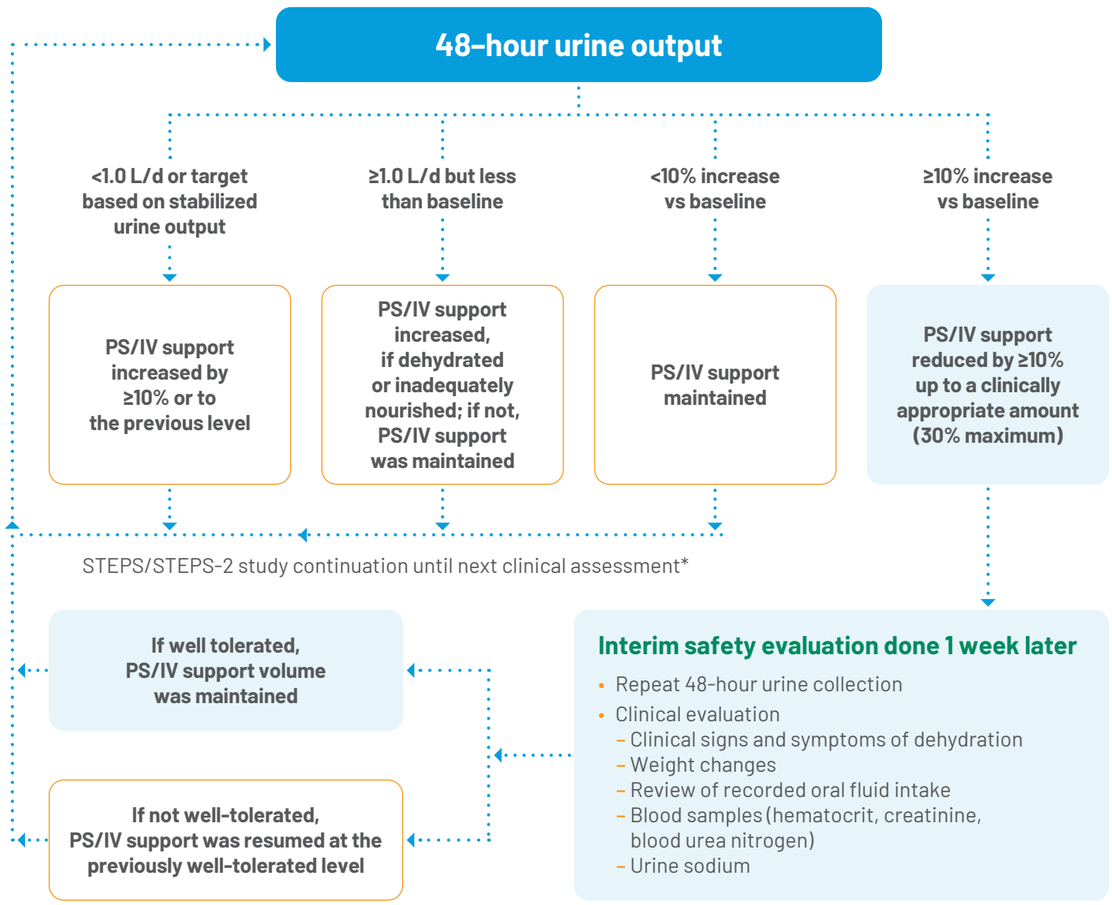
Stabilization

- Oral fluid intake and urine output remained ±25% from optimized level
- PS was stable when:
  - Actual PS matched prescribed volume
  - 48-hour oral fluid intake and urine output ±25% of baseline
  - Urine output 2–4 L/48 hours
- No further PS adjustments during stabilization

Patients were randomized into the STEPS study once optimized and stabilized for ≥4 weeks.[15]

PS MODIFICATIONS AND MONITORING (STEPS AND STEPS-2 WEANING PROTOCOL)[15,16]

PS/IV support reductions were spread across all days



*Baseline urine output is the urine volume obtained during the stabilization period before initiating treatment

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

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.

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In STEPS and STEPS-2 studies, once a patient was optimized and stable, parenteral support (PS) infusions were slowly reduced over time.[15,16] Gradual reductions minimize the risk of dehydration and increase the likelihood of weaning success.[3]

Reductions in parenteral support (PS) are often made in one of the following ways[2,3]:

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

STEPS and STEPS-2 relied on urine output, but alternative approaches are available[2,13]

- Nutrition-focused physical assessment
- Stool output
- Oral intake
- Electrolyte and micronutrient levels
- Body weight

Evaluating weaning in terms of intake, output, and other clinical measures

The overall approach for weaning PS may consider[2,3]:

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

Discussing the weaning process with your patients can help guide an appropriate approach

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MONITORING HYDRATION AND NUTRITIONAL STABILITY DURING AND AFTER PS WEANING

Routine monitoring often happens throughout the PS weaning process[2,3]

Routine blood samples/labs such as CBC, BUN, and creatinine are commonly evaluated. During PS weaning, adjustments to medications for SBS symptoms may need to be made; electrolyte, nutrient, and vitamin levels monitored for deficiencies; renal function evaluated; and adequate fluid intake achieved with an oral rehydration solution (ORS). See a more exhaustive list to the right of parameters often monitored throughout the PS weaning process.

After your patient has achieved their PS weaning goal, long-term monitoring of hydration and nutrition status is recommended[3]

Monitor electrolytes, trace elements, vitamins and minerals

Monitor weight for nutritional status

Antidiarrheal medications should be continued and adjusted based on stool volume (stoma), frequency and consistency

Adequate energy and fluid intake and sustained hydration should be reinforced at each visit[2,3]

ONGOING MONITORING

Parameters monitored in STEPS study[17,18]

(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[18]

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

→ Fat-soluble vitamins and micronutrients

Abbreviations: 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; PN, parenteral nutrition; PT, prothrombin time; PTT, partial thromboplastin time; TSH, thyroid-stimulating hormone.

If a patient cannot maintain adequate hydration or nutrition status after full PS weaning, PS should be restarted.[3]

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WEANING PARENTERAL SUPPORT (PS) CASE STUDY

EVAN,
32-YEAR-OLD MALE WITH SHORT BOWEL SYNDROME (SBS)*

History
- Medically refractory Crohn's disease
- Treated with a biologic for 10 years
- Small bowel resection and jejunocolonic anastomosis
- Colon-in-continuity
- PS usage: 2 years
- Weight: 64 kg (140 lbs)
- BMI: 20.5

Current nutrition strategy
- 1.8 L of PS infused over 10 hours, 5 days/week
- ~1600 kcal/day, 75 mEq/day sodium, 307 kcal/day, 203 g dextrose

Symptoms of malabsorption
- Diarrhea
- Weight loss
- Dehydration
- Muscle cramping

"Instead of spending time hooked up to PS, I spend it doing what I love with the people I love!"

ACTOR PORTRAYAL

Observations
- Limits oral intake due to excessive diarrhea
- Deficient in magnesium and zinc
- Activities of daily living impacted by burden of symptoms
- Plans life around PS infusions and staying close to the nearest bathroom
- Various medications being used for symptom management (i.e. loperamide, ranitidine, tincture of opium)

*Hypothetical patient. Individual results may vary.

EVAN'S PERSONALIZED TREATMENT PLAN

Preparation
- Established treatment goal: eliminate parenteral support (PS) therapy
- Patient education: Monitoring diet and hydration, the weaning process, and GATTEX therapy
- Coordinated with his multidisciplinary care team

Optimization: Month 0
- Monitored hydration and nutrition
- PS sodium was adjusted for higher sodium provision
- Urine/serum sodium was normal on retest—serum sodium was 140 mEq/L and urine sodium was undetectable
- Added GATTEX (initial safety monitoring results—colonoscopy and blood tests—were normal)
- Adverse event (abdominal discomfort) resolved spontaneously

PS modification and patient monitoring: Month 6
- Frequent interactions with MDT for monitoring of nutritional and hydration status
- Began PS volume adjustments
- **Month 12 results: Infusions reduced to 3 days/week (infusing 1.5 L over 8 hours/day)**
  - Weight: 63 kg (139 lbs)
  - Urine output: ≥1.0 L/day
  - Oral intake: ≥80% of caloric goal met
- **Month 18 results: PS elimination is achieved**

Ongoing monitoring: 18+ Months
- Continues to receive GATTEX injections daily
- Adequate hydration and nutrition are maintained
- **At 19 months: central venous catheter is removed**
- Receives oral vitamin and mineral supplementation, encouraged hyperphagia
- Continuous monitoring of:
  - Oral hydration and nutrition
  - Weight
  - Lab work
  - Signs/symptoms of AE due to GATTEX
  - Vitamin, mineral, and electrolyte levels

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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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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.

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Warnings and Precautions (continued)

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

GATTEX IS THE FIRST AND ONLY FDA-APPROVED ANALOG OF NATURALLY OCCURRING GLP-2[14]*

In clinical studies of patients with SBS, GATTEX was proven to[14]:

Significantly reduce weekly PS **VOLUME** requirements

In a 6-month pivotal study, adult patients treated with GATTEX reduced weekly PS volume by ≥20% (27/43) vs placebo (13/43) at Weeks 20 and 24; *P*=0.002, the primary endpoint.

Help patients achieve more **TIME** off of PS

In the same study, adult patients achieved a reduction of ≥1 day off PS per week (21/39) vs placebo (9/39), an exploratory endpoint.

Help some patients achieve complete **FREEDOM** from PS

In a 24-month open-label extension, adult patients previously treated with GATTEX in the pivotal study weaned off PS completely after 30 months of treatment (10/30)—the average duration was ~20 months.

In a 6-month pivotal study, pediatric patients ≥1 year treated with GATTEX reduced weekly PS volume by ≥20% (18/26), the primary endpoint. They also achieved a reduction of ≥1 day off PS per week (10/26)—mean PS infusion time at baseline was 7 days/week—and patients weaned off PS completely (3/26), secondary endpoints.

*GLP-2=glucagon-like peptide-2.

LEARN HOW GATTEX CAN HELP REDUCE PARENTERAL SUPPORT (PS) AT **weaningps.com**

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