enterra medical™

Based on your survey responses Enterra Therapy might not be right for you at this time.

Enterra™ Therapy Discussion Guide

This guide will explain general criteria typically used to evaluate Enterra Therapy eligibility to help start a conversation with your doctor.

*Humanitarian Device. Authorized by Federal law for use in the treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years. The effectiveness of this device for this use has not been demonstrated.

Enterra Therapy Eligibility

Enterra Therapy* is indicated for people who:

- ☑ have gastroparesis due to diabetes or an idiopathic (unknown) cause
- ☑ are 18-70 years old
- ☑ have chronic, intractable (has not responded to medication) nausea and vomiting

Are you unsure if you have gastroparesis?

Find a Gastroenterologist (GI) in your area who specializes in gastroparesis.

Preparing for your Appointment

My Next Appointment: _____/_____/_____

To give your doctor examples of the issues you have experienced, mark the severity and frequency of symptoms by using the following scores:

Severity:

0 = absent
1 = mild (not influencing normal activities)
2 = moderate (diverting from, but not urging modification of, usual activities)
3 = severe (influencing usual activities severely enough to urge modifications)
4 = extremely severe (requesting bed rest)

Frequency:

0 = absent
1 = rare (1 time/week)
2 = occasional (2-4 times/week)
3 = Frequent (5-7 times/week)
4 = extremely frequent (> 7 times/week)

SYMPTOM	SEVERITY	FREQUENCY
1. Vomiting **Definition**: Forceful expulsion of stomach content from the mouth. It should be distinguished from retching, which is defined as "heaving as if to vomit."		
2. Nausea **Definition**: Feeling sick to your stomach as if you were going to vomit.		
3. Early satiety **Definition**: A feeling that the stomach is over-filled soon after starting to eat so that you are not able to finish a normal-sized meal.		
4. Bloating **Definition**: Feeling like you need to loosen your clothes. Stomach or belly is visibly larger.		
5. Postprandial fullness **Definition**: Feeling excessively full after meals.		
6. Epigastric pain **Definition**: The epigastrium can be identified as an area approximately the size of one hand in the central part of the upper abdomen. The pain should be distinguished from discomfort, which is defined as a subjective, negative, and unpleasant feeling that "does not hurt."		
7. Epigastric burning **Definition**: Burning is a special type of pain that can be described as an "inside flame."		

Preparing for your Appointment

Bring this form with you to your appointment. Your physician can determine if gastroparesis screening is appropriate.

Symptoms (Start Date/Severity 1-10): Nausea:_____/_____ Vomiting:_____/_____ Early Satiety:_____/_____
Bloating:_____/_____ Abdominal Pain:_____/_____
How Quickly Do You Vomit After Meal: ☐ 5-15 min ☐ 30 min ☐ 1-2 hrs ☐ 4+ hrs

Weight Loss: _____lbs _____weeks
Doctor's Office Visits In Last Year Because of Symptoms: _____
ER/Hospital Visits In the Last Year Because of Symptoms: _____
Quality of Life Impact (How Has This Affected Work/Family Life?):_____

Diagnostics

Gastric Emptying Study Results (Off Prokinetics for 3 Days):% Retention 2 hrs_____ 4 hrs_____
Smart Pill Study Results: Gastric Emptying_____ Small Intestinal Transit_____ Colonic Transit_____
EGD Results:_____ **CT Results:**_____

Etiology

☐ Is the patient **Diabetic**? ☐ Type 1 or ☐ Type 2 Duration:_____ Current Blood Sugar:_____mg/dl:_____HbA1c
Test for Neuropathy?_____ Renal Insufficiency?_____
Prior Acute **Viral Illness** Suggestive of Post-Viral Gastroparesis? _____
Narcotic Use? Name:_____Dose:_____Duration:_____
Medication Induced: ☐ GLP-1 agonists ☐ Octreotide ☐ Anticholinergics ☐ Calcium Channel Blockers
☐ Levodopa ☐ Digoxin ☐ Other:_____

Neuromuscular Disorder (Polymyositis, Dermatomyositis, etc.):_____
☐ **Thyroid Dysfunction (hyperthyroidism)** ☐ **Infiltrative Disorders (amyloidosis, lymphoma, etc.)**
☐ **Auto-immune Disorders (Lupus, Scleroderma, Sjogren's, etc.)**

Previous Abdominal Surgery (Fundoplication, Billroth I/II, etc.):_____
☐ **Prior Eating Disorder** ☐ **Other Cause:**_____ ☐ **Cause Unknown/Idiopathic**

Frontline Therapies

Dietary Modification:_____
Supplemental Nutrition: Oral Supplement ☐ NJ Tube ☐ GJ Tube ☐ J Tube ☐ TPN

Medications

Prokinetics

☐ Metoclopramide: Dose_____ Duration_____
☐ Erythromycin: Dose_____ Duration_____
☐ Prucalopride: Dose_____ Duration_____
☐ Other:_____Dose_____ Duration_____

Antiemetics

☐ Ondansetron : Dose_____ Duration_____
☐ Promethazine: Dose_____ Duration_____
☐ Prochlorperazine: Dose_____ Duration_____
☐ Scopolamine: Dose_____ Duration_____
☐ Other:_____Dose_____ Duration_____

Further Therapies, if Diagnosed with Gastroparesis

☐ Gastric Electrical Stimulation (Enterra™ Therapy) ☐ Pyloric Botox ☐ Pyloroplasty ☐ Gastrectomy/Roux-en-Y
☐ Other ☐ None

At the Appointment

What questions might you have for your doctor?

Write them down and keep track of how your doctor answers.

Q: _____

_____

A: _____

_____

Q: _____

_____

A: _____

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Q: _____

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A: _____

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Q: _____

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Q: _____

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A: _____

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Q: _____

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A: _____

_____

The FDA approved the Humanitarian Device Exemption for Enterra Therapy in 2000.
In 2022, Enterra Medical assumed commercial responsibility of Enterra Therapy.

Enterra Medical is dedicated to helping more people with chronic gastroparesis live better lives through advancing technology, bolstering clinical science, and accelerating patient access to Enterra Therapy.

The information provided in this brochure is for general educational purposes only and is not a substitute for professional medical advice, diagnosis or treatment. Always talk to your doctor about the best treatment options for your individual situation.

Important Safety Information
Enterra Therapy for treatment of chronic, resistant to medication nausea and vomiting associated with gastroparesis caused by diabetes or an unknown origin in patients aged 18 to 70 years: patients should always discuss potential risks and benefits of the device with their physician.

Indications for Use: The Enterra Therapy System for gastric electrical stimulation is indicated for use in the treatment of chronic, intractable (drug refractory) nausea and vomiting associated with gastroparesis caused by diabetes or an unknown origin in patients aged 18 to 70 years.

Contraindications: The Enterra Therapy System is not intended for patients whom the physician determines are not candidates for surgical procedures and/or anesthesia due to physical or mental health conditions. You cannot have diathermy (deep heat treatment from electromagnetic energy) if you have an Enterra device. Patients with Enterra should not have magnetic resonance imaging (MRI).

Warnings/Precautions/Adverse Events: This system has not been evaluated for pregnant women, for use in patients under the age of 18, or patients over the age of 70. The system may be affected by or adversely affect cardiac devices. Strong sources of electromagnetic interference (EMI) such as from electrocautery, defibrillation/cardioversion, therapeutic ultrasound, radiofrequency (RF)/microwave ablation, or MRI, can result in serious injury, system damage, or operational changes to the system. EMI, postural changes, or other activities may cause shocking or jolting sensations. Patients on anticoagulation therapy may be at a greater risk for post-operative complications. The use of non-Medtronic components with this system may result in damage to Medtronic components, loss of therapy, or patient injury. There is the possibility of an allergic or immune system response to the implanted materials. When possible, a physician is to identify and treat any infections prior to surgery. Infections at the implant site almost always require the surgical removal of the implanted system. The lead can become entangled with the bowel or perforate your stomach and cause life-threatening blockage or infections that require immediate medical attention and may require surgery. Patients should avoid activities that may put undue stress on the implanted system components (activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching that can cause component fracture or dislodgement). Adverse events related to the therapy, device, or procedure can include: infection, pain at the surgery site, device components may wear through the skin, bruising at the neurostimulator site, bleeding, loss of therapeutic effect, undesirable change in stimulation (described as a jolting, shocking, or burning sensation), gastrointestinal symptoms and gastrointestinal complications (in that the lead may perforate your stomach or device components may become entangled with or obstruct other internal organs, requiring surgery). The system could stop because of battery depletion or mechanical or electrical problems. Any of these situations may require additional surgery or cause your symptoms to return.

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For further information, please contact Enterra Medical at info@enterramedical.com.
USA Rx only.

www.enterramedical.com

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