

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

# Enterra<sup>®</sup> Therapy Discussion Guide

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





## 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

### 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."

## SEVERITY

## FREQUENCY

# 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: \_\_\_\_\_

Q: \_\_\_\_\_

A: \_\_\_\_\_

Q: \_\_\_\_\_

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Q: \_\_\_\_\_

A: \_\_\_\_\_

Q: \_\_\_\_\_

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**

**Intended Use:** The Enterra® Therapy System is an implanted device that provides gastric stimulation to treat chronic, intractable, nausea and vomiting that is not well treated by drugs or other means in patients aged 18 to 70 years caused by diabetes or an unknown origin.

**Contraindications:** Enterra Therapy is only for patients who are healthy enough for surgical procedures and/or anesthesia. Once implanted, patients need to avoid diathermy, which is deep heat treatment from electromagnetic energy, as it may cause injury or device failure.

**Warnings:** Enterra Therapy has not been studied in pregnant women, patients under the age of 18, or over 70. Issues may occur if the system interacts with other implanted devices such as pacemakers. Patient injury or device failure may be caused by other medical treatments such as electrocautery, defibrillation/cardioversion, therapeutic ultrasound, or radiofrequency (RF)/microwave ablation. Patient activities may cause shocking or jolting sensations.



The Enterra II System is MR Conditional. This means that patients with the Enterra II System can safely have MRI examinations of some body parts under certain conditions. Consult your doctor to determine if you are eligible for MRI examination.

**Risks:** Potential risks include infection, pain at the surgery site, allergic or immune system response, lead and bowel twist together, device wearing through the skin, bruising, bleeding, loss of therapeutic effect, jolting, shocking, burning sensation, gastrointestinal or stomach issues, loss of therapy due to component failure or battery wear out, or perforated stomach which may cause life-threatening blockage or infections that require immediate medical attention including surgery. Risks can be minimized by avoiding activities such as sudden, excessive, or repetitive bending, twisting, bouncing, or stretching.

**Humanitarian Device:** Authorized by Federal law for the intended use described above. The effectiveness of this device has not been demonstrated.

Always discuss potential risks and benefits of the device with your physician.

For further information, please contact Enterra Medical at [info@enterramedical.com](mailto:info@enterramedical.com).

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[www.enterramedical.com](http://www.enterramedical.com)

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