

## KAEMMERER GROUP, LLC PORTFOLIO EXAMPLE

- Client:** Medtronic, Inc.
- Project:** Monograph for healthcare payers on electrical neurostimulation for gastroparesis
- Objective:** This 16-page monograph sets the stage for healthcare payers to be willing to pay for a new therapy for a rare disease.
- Description of monograph:** This monograph explains the rare condition of gastroparesis, the various treatment options for this condition, and introduces a Medtronic therapy that has a Humanitarian Device Exemption for gastroparesis, Enterra® Therapy. Clinical literature is summarized and referenced.

### Visual elements

Because the audience for this monograph is healthcare payers and Medtronic's message was to educate rather than to make a sale, we deliberately chose a simple, two-color format.

The treatment algorithm (see blue box at right) is something that communicates efficiently to our audience of healthcare payers. It indicates the steps that a doctor would take in the process of diagnosing gastroparesis and in what order treatment options would be used to address symptoms. Note that Enterra Therapy is near the bottom of the treatment algorithm. This indicates that it is appropriate to treat the condition with other more conservative therapies before considering Enterra Therapy which involves an implantable medical device.

### Copy close-up

"Prokinetic drugs can be used to promote gastric emptying. Metoclopramide (Reglan®), which has both prokinetic and antiemetic properties, is the only drug approved for the treatment of diabetic gastroparesis. Metoclopramide has central dopanergic actions that may result in such severe central nervous system side effects that 10% of patients are required to withdraw from medication. Controlled studies have shown that cisapride (Propulsid®) can improve gastric emptying, but not other symptoms of gastroparesis.<sup>3-7</sup> ... Prokinetic drugs are associated with side effects such as cardiac arrhythmias, abdominal cramping, diarrhea, and nervousness."

[End of excerpt.]

Note the didactic, factual style of the writing, which is appropriate to the audience for the piece and its purpose. Clinical literature is referenced throughout the monograph.



**Kaemmerer Group, LLC**  
Medical Marketing Communications

for GASTROPARESIS

**What are the current treatment options for gastroparesis?**

Treatment options for chronic gastroparesis include diet modification, drug therapy, nutritional therapy, and surgery. Patients may initially be treated with diet modifications. If these alone are unsuccessful, antiemetic and/or prokinetic drugs are generally tried. If symptoms cannot be controlled with medication, it may be necessary to use supplemental nutritional therapy to maintain hydration and the patient's nutritional status.

- The purpose of *diet modification* is to reduce symptoms and maintain adequate fluids and nutrition. A modified diet consists of liquids, restricted fats, frequent small meals, and avoidance of plant fiber. Liquids prevent dehydration and keep the body supplied with salts and minerals. Fats are restricted because they delay stomach emptying, and plant fiber is avoided because it cannot be digested.
- Prokinetic drugs* can be used to promote gastric emptying. Metoclopramide (Reglan®), which has both prokinetic and antiemetic properties, is the only drug approved for the treatment of diabetic gastroparesis. Metoclopramide has central dopanergic actions that may result in such severe central nervous system side effects that 10% of patients are required to withdraw from medication. Controlled studies have shown that cisapride (Propulsid®) can improve gastric emptying, but not other symptoms of gastroparesis.<sup>3,7</sup> In 2000, Propulsid was removed from the U.S. market due to deaths from cardiac arrhythmias. The use of other drugs with known prokinetic properties (e.g., erythromycin and tegaserod (Zelnorm®)) in the treatment of gastroparesis has also been reported in the literature. Prokinetic drugs are associated with side effects such as cardiac arrhythmias, abdominal cramping, diarrhea, and nervousness.

Treatment Algorithm	
History/Physical Exam	Patient History Neurological Assessment Blood Tests Drug Screening Immunological Tests
Diagnostic Testing	Upper GI Endoscopy Upper GI Barium Series Solid-phase Emptying Studies Electrogastrogram (EGG)
Diagnosis of Gastroparesis	
Diet Modification	Liquids Low-fat Frequent small meals Restricted plant fiber
Medication	Prokinetics (Reglan, etc.) Antiemetics (Phenergan, etc.)
Enteral Nutrition	Direct delivery of nutrients to intestinal tract via a feeding tube
Enterra Therapy	Electrical stimulation of stomach via a fully implantable system
Total Parenteral Nutrition (TPN)	Direct delivery of nutrients to bloodstream via an indwelling intravenous catheter
Other Surgical Options	Gastrectomy

Note: Any combination of diet modification, medication, nutritional support, and Enterra Therapy may be used to control symptoms in an individual patient.

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