

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DIRECTOR**

**ACTION REFERRAL**

TO <i>Bowling</i>	DATE <i>11/22/06</i>
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DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER <i>CC0370</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR <i>Cleaved 11/21/07 see Attached letter.</i>	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE <i>12/5/06</i>
	<input type="checkbox"/> FOIA DATE DUE _____
	<input type="checkbox"/> Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			



**Medtronic**

Medtronic Gastroenterology and Urology  
4000 Lexington Avenue North  
Shoreview, MN 55126  
www.medtronic.com

763-514-9500  
763-514-9424

November 17, 2006

**RECEIVED**

Robert M. Kerr

Director

Department of Health & Human Services

P.O. Box 8206

Columbia, SC 29202-8206

NOV 22 2006

Department of Health & Human Services  
OFFICE OF THE DIRECTOR

Re: Gastric Electrical Stimulation for Gastroparesis

Dear Director:

I would like to introduce myself, my name is Carolyn Pine and I work for Medtronic with the responsibilities of resolving coverage and payment issues for our customers.

Effective January 1, 2007, there will be new CPT<sup>45</sup> codes to describe Gastric Electrical Stimulation. The new codes were not assigned RVU's and will require carrier pricing, both by government and commercial carriers. Those codes are:

CPT <sup>45</sup> Codes for 2007
43647 Laparoscopy, surgical, implantation or replacement of gastric neurostimulator electrodes, antrum
43648 Laparoscopy, surgical, revision or removal of gastric neurostimulator electrodes, antrum
43881 Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882 Revision or removal of gastric neurostimulator electrodes, antrum, open
95999 Unlisted neurological or neuromuscular diagnostic procedure

**Background-** Enterra<sup>®</sup> Therapy is indicated for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic origin. It is contraindicated in patients whom the physician determines are not suitable candidates for surgical procedures due to physical or mental conditions. Enterra Therapy is a reversible therapy that involves electrical stimulation of the lower stomach (antrum). Electrical stimulation is accomplished via a fully implantable system that consists of two single-electrode intra-muscular leads and a neurostimulator.

The Enterra Therapy System for gastroparesis received Humanitarian Device Exemption (HDE) approval from the FDA in March 2000. The HDE authorizes Medtronic to market the Enterra Therapy System provided the device is used in medical centers in which the center's Institutional Review Board (IRB) has approved use of the device. IRB approval for individual patients is not required.

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**Our Request-** In order to provide our customers with the most up-to-date information, we would like clarification on the following issues:

1. For these carrier priced codes, will physicians be required to provide operative reports for manual pricing? If so, will this process be required for the entire calendar year, or will a fee schedule be assigned once enough data has been received?
2. When will these codes and carrier pricing be implemented?
3. If the physician submits claims electronically, how can they submit supporting documentation? Should there be a comment in box 19 on the CMS1500? Please provide any special billing instructions, if appropriate.
4. If your company is part of an association, does your response speak for the entire association?

Would a DVD showing a Gastric Electric Stimulation implant be of assistance to you and your staff in the developing the pricing of the CPT codes? Would your company be interested in a presentation by a physician involved with Gastric Electrical Stimulation? The presentation will provide an overview of Enterra Therapy and would be eligible for one hour of CEU credits for case managers. If interested, please respond to me by email or fax. My contact information is listed below.

We appreciate your assistance in answering the above questions. Please let us know if you need additional information.

Sincerely,



Carolyn A. Pirie  
Principal Consultant  
Medtronic Gastroenterology and Urology  
Economic Solutions Group  
3535 Travis, Suite 210  
Dallas, Texas 75204  
Tele: 214-599-9394  
Fax: 214-522-0474  
[Carolyn.ann.pirie@medtronic.com](mailto:Carolyn.ann.pirie@medtronic.com)

Enclosure: Enterra Therapy CPT Coding Comparison for 2006 and 2007



# Medtronic

## ENTERRA® THERAPY FOR GASTROPARESIS

### Coding Comparison for 2006 and 2007

Medtronic has compiled this coding information for your convenience. It is always the provider's responsibility to determine coverage and submit appropriate codes, modifiers, and charges for the services that were rendered. Contact your local carrier/payer for interpretation of appropriate coverage and coding policies. For unapproved uses, consult with your local carrier/payer before seeking reimbursement for use of a product that may be inconsistent with or not expressly specified in the FDA cleared or approved labeling (manual). Some payors may have policies that make it inappropriate to submit claims for such items or related services.

The Economic Solutions Group of Medtronic Gastroenterology and Urology is available to respond to your coding questions toll-free at **800-292-2903**, extension 50026.

There have been significant CPT coding changes for filing claims in 2007. This document provides a crosswalk from the codes for 2006 to the codes that will be effective in 2007.

Laparoscopic Procedure Implantation	CPT <sup>1</sup> Codes for 2006	CPT <sup>1</sup> Codes for 2007
	<b>64999</b> Unlisted procedure, nervous system. (Use for implantation, revision or removal of neurostimulator leads(s), open or laparoscopic approach)	<b>43647</b> Laparoscopy, surgical, implantation or replacement of gastric neurostimulator electrodes, antrium
	<b>64590</b> Insertion or replacement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling <sup>2</sup>	<b>Same as 2006</b> <b>64590</b> Insertion or replacement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling <sup>2</sup>
Revision/ Removal	<b>64595</b> Revision or removal of peripheral neurostimulator pulse generator or receiver	<b>43648</b> Laparoscopy, surgical, revision or removal of gastric neurostimulator electrodes, antrium
Open Procedure Implantation	<b>43999</b> Unlisted procedure, stomach (Use for open approach for implantation, revision or removal of leads(s)) <b>OR</b> <b>43659</b> Unlisted laparoscopy procedure, stomach (Use for laparoscopic approach for implantation, revision, or removal of lead(s))	<b>43881</b> Implantation or replacement of gastric neurostimulator electrodes, antrium, open
	<b>64590</b> Insertion or replacement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling <sup>2</sup>	<b>Same as 2006</b> <b>64590</b> Insertion or replacement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling <sup>2</sup>

Use **43881** for all implantation.

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<sup>2</sup> In a replacement, coding guidelines do not allow removal of the old device to be coded together with implantation of the new device



*State of South Carolina*  
*Department of Health and Human Services*

Mark Sanford  
Governor

Robert M. Kerr  
Director

January 2, 2007

Ms. Carolyn A. Pirie  
Principal Consultant  
Medtronic Gastroenterology and Urology  
Economic Solutions Group  
3535 Travis, Suite 210  
Dallas, Texas 75204

Dear Ms. Pirie:

Thank you for your letter regarding coverage information for Enterra® Therapy or Gastric Electrical Stimulation for Gastroparesis. The South Carolina Department of Health and Human Services has reviewed all additions, deletions, and changes to the 2007 Current Procedural Terminology (CPT).

At this time, the new CPT codes 43647, 43648, 43881 and 43882 will not be covered by the South Carolina Medicaid program. CPT code 95999 will be covered, but requires supporting documentation to justify its use as an unlisted code, the complexity of the service, and the charge. Support documentation must be submitted as a hard copy with the documentation attached. The use of 95999 in relation to Gastric Electrical Stimulation will not be approved for payment.

Any additional clinical information regarding Enterra® Therapy to assist in future policy development is welcomed and should be forwarded to our Medical Director at the address below.

South Carolina Department of Health and Human Services  
Attention: Medical Director  
Post Office Box 8206  
Columbia, SC 29202

If you have any other questions, you may contact Ms. Jennifer Campbell, Team Leader in the Division of Physician Services at (803) 898-2660.

Sincerely,

*Susan B. Bowling*  
Susan B. Bowling  
Deputy Director

SBB/gwd