

**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 11/21/06 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

NOV 22 2006

Robert M. Kerr
Director
Department of Health & Human Services
P.O. Box 8206
Columbia, SC 29202-8206

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 CPT⁴⁵ 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:

CPT⁴⁵ 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[®] 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
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Dallas, Texas 75204
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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 ¹ Codes for 2006	CPT ¹ Codes for 2007
	64999 Unlisted procedure, nervous system. (Use for implantation, revision or removal of neurostimulator leads(s), open or laparoscopic approach)	43647 Laparoscopy, surgical, implantation or replacement of gastric neurostimulator electrodes, antrum
	64590 Insertion or replacement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling ²	Same as 2006 64590 Insertion or replacement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling ²
Revision/ Removal	64595 Revision or removal of peripheral neurostimulator pulse generator or receiver	43648 Laparoscopy, surgical, revision or removal of gastric neurostimulator electrodes, antrum
Open Procedure Implantation	43999 Unlisted procedure, stomach (Use for open approach for implantation, revision or removal of leads(s)) OR 43659 Unlisted laparoscopy procedure, stomach (Use for laparoscopic approach for implantation, revision, or removal of lead(s))	43881 Implantation or replacement of gastric neurostimulator electrodes, antrum, open Use 43881 for all implantation.
	64590 Insertion or replacement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling ²	Same as 2006 64590 Insertion or replacement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling ²

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² 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

Log #370
✓

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