

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF DIRECTOR

ACTION REFERRAL

TO	DATE
Bushling	7-14-06

DIRECTOR'S USE ONLY		ACTION REQUESTED	
1. LOG NUMBER	000080	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____	
2. DATE SIGNED BY DIRECTOR	Cleared 8/9/06 attached. ✓	<input checked="" type="checkbox"/> Prepare reply for appropriate signature DATE DUE 7-25-06  <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 Gastroenterology and Urology  
Economic Solutions Group

Stephanie Nelson-Wirmer  
19 Bedros Street  
Windham, New Hampshire 03087  
603/421-9162

July 14, 2006

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

Via Fax: 803-898-4515/ Total Pages 2

Dear Mr. Kerr:

My name is Stephanie Nelson Wirmer. I am the field representative for Medtronic Urology. Parts of my responsibilities include working with physicians, facilities and payors regarding coverage and payment issues relating to our products.

We continue to receive requests from physicians to clarify certain coverage and payment issues relating to our product InterStim or sacral nerve stimulation. InterStim Therapy involves electrical stimulation of the sacral nerves (in the lower region of the spine) via an implantable system that includes a lead, neurostimulator, and an extension which connects the lead to the neurostimulator. The therapy has been available for commercial use in Europe since 1994. It was FDA approved for commercial release in the U.S. for the treatment of urge incontinence in 1997. In 1999, approval was expanded to include significant symptoms of urgency-frequency and non-obstructive urinary retention. The indications were later revised (2002) to include the term overactive bladder. InterStim Therapy was approved for use following a test stimulation trial using a temporary lead and an external stimulator. In August 2001, the FDA approved use of the chronic (implant) lead with an externalized extension (Staged Implant) as an additional test to determine whether a patient would benefit from the therapy.

With InterStim Therapy, test stimulation is done to determine whether the patient is likely to benefit from the therapy. Test stimulation involves the placement of a test lead connected to an external power source for up to seven days. This allows patients to temporarily experience stimulation and the effect it has on controlling urinary symptoms and make an informed choice about the risks and benefits of pursuing the therapy. Patients keep diaries of their voiding behavior for several days prior to the test and during the test period. If the patient's voiding behavior is significantly improved and test stimulation is deemed successful, implant of the InterStim System may proceed. If this test is not successful, the additional test described above may be undertaken using the implanted (chronic) lead plus an external test stimulator. If this test proves successful, the chronic stimulator may be implanted and connected to the existing chronic lead.

We would appreciate your providing us with answers to the following questions:

1. Are the codes 64561, 64581, 64590, 64585, 64595 and 95972 covered benefits for South Carolina Medicaid? If so, what are the physician allowables for these codes in both the facility and non-facility settings?
2. Which of these codes (if any) require prior authorization?
3. Is there a special form to be used for prior authorization? If so, could you supply either a copy of the form or the url where it can be downloaded?

 **Medtronic**  
Economic Solutions Group

*Stephanie Nelson-Wirmer*  
*Approved - Sign*

JUL 14 2006  
Department of Health & Human Services  
OFFICE OF THE DIRECTOR

Medtronic Gastroenterology and Urology  
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4. How is the hospital reimbursed for the outpatient procedures? (See cpt codes noted above).
5. How is the hospital reimbursed for the device component for outpatient procedures? The applicable L codes and C codes are listed below:

Sacral nerve stimulation test lead, each	A4290	
InterStim Therapy Test Kit		C1897
Implantable neurostimulator electrode, each (each lead has four electrodes)	L8680	C1778
Implantable neurostimulator pulse generator single array non rechargeable, includes extension	L8686	C1767
Implantable extension		C1883
Patient programmer (external) for use with implantable programmable neurostimulator	L8681	C1787
Lead introducer		C1894

6. If the procedure codes are not covered, what are the steps for a physician to request coverage?
7. If there is no mechanism for device reimbursement (via revenue code 278; etc.), what is the mechanism for requesting such payment mechanism be put in place?
8. Is the procedure covered in an ASC setting?

We look forward to working with you in the near future. If you have questions concerning any of the above questions, please feel free to call at 603-421-9162 or email me at Stephanie.N.Wimmer@Medtronic.com.

Sincerely:



Stephanie Nelson Wimmer, MBA, MPH  
Principal/Economic Solutions Consultant  
Medtronic, Inc. Gastroenterology Urology  
Windham, NH 03087



**Medtronic**  
Economic Solutions Group



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

Mark Sanford  
Governor

Robert M. Kerr  
Director

August 9, 2006

Ms. Stephanie Nelson-Wimmer  
Medtronic Gastroenterology and Urology  
Economic Solutions Group  
19 Bedros Street  
Windham, New Hampshire 03087

RE: InterStim or Sacral Nerve Stimulation

Dear Ms. Nelson-Wimmer:

Thank you for the letter to Mr. Robert Kerr, Director of the Department of Health and Human Services (DHHS), regarding coverage information for InterStim or Sacral Nerve Stimulation. We will address the answers to your questions as presented.

- 1) Are the codes 64561, 64581, 64590, 64585, 64595, and 95972 covered benefits for South Carolina Medicaid? If so, what are the physician allowables for these codes in both the facility and non-facility settings?

CPT Code	Non-facility	Facility
64561	\$1028.26	\$285.54
64581	\$567.43	\$567.43
64590	\$269.66	\$137.34
64585	\$371.95	\$122.83
64595	\$337.59	\$106.99
95972	\$80.10	\$60.49

- 2) Which of these codes (if any) require prior authorization?

None of the codes listed require prior authorization. However, CPT code 64590 does require support documentation attached to the claim to support medical necessity.

- 3) Is there a special form to be used for prior authorization? If so, could you supply either a copy of the form or the URL where it can be downloaded?

Although the procedure codes listed above do not require prior authorization, the process and the required form can be found in the SC Medicaid Physician's Provider manual, pages 2-194 to 2-200, located on our web page at: [www.scdhhs.gov](http://www.scdhhs.gov) under Provider's Information.

Log #80  
✓

Ms. Stephanie Nelson-Wimmer

August 9, 2006  
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- 4) How is the hospital reimbursed for the outpatient procedures? (See cpt codes noted above.)  
SC Medicaid reimburses surgical procedures by CPT code. Each covered CPT code is assigned an all-inclusive surgical rate. Other services such as clinics, ER and treatment, testing and therapies are reimbursed a specific rate by revenue code.
- 5) How does the hospital reimburse for the device component for outpatient procedures? The applicable L codes and C codes are listed below:  
Covered devices are considered a part of the procedure and are included in the all-inclusive surgical rate. Covered devices are not separately reimbursed.
- 6) If the procedure codes are not covered, what are the steps for a physician to request coverage?  
This is not applicable since all codes listed in question one are covered by the SC Medicaid system.
- 7) If there is no mechanism for device reimbursement (via revenue code 278; etc.), what is the mechanism for requesting such payment mechanism be put in place?  
Our reimbursement methodology does not allow us to separately reimburse for devices.
- 8) Is the procedure covered in the ASC Setting? No. The SC Medicaid Program follows the guidelines set by Medicare for the procedures that are allowed for reimbursement in the Ambulatory Surgical Center setting.

If you have additional questions, you may contact Mr. William Feagin, in the Division of Physician Services, at (803) 898-2660.

Sincerely,



Melanie "Bz" Giese, RN  
Bureau Director

MG/wd