COMMONLY BILLED CODES

SACRAL NEUROMODULATION FOR BLADDER CONTROL OR BOWEL CONTROL

EFFECTIVE JANUARY 2019

Medtronic

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The following information is calculated per the footnotes included and does not take into effect Medicare payment reductions resulting from sequestration associated with the Budget Control Act of 2011. Sequestration reductions went into effect on April 1, 2013.

FOR QUESTIONS PLEASE CONTACT US AT NEURO.US.REIMBURSEMENT@MEDTRONIC.COM

ICD-10-CM[1] Diagnosis Codes

Diagnosis codes are used by both physicians and hospitals to document the indication for the procedure.

InterStim Therapy is used for bladder control and bowel control. InterStim Therapy for Bladder Control is directed at addressing specific urinary symptoms. InterStim Therapy for Bowel Control is directed at addressing the symptom of chronic fecal incontinence. Symptom codes are assigned as the principal diagnosis when the underlying cause is not known or not documented. However, if the underlying cause is known, then the cause is sequenced as the principal diagnosis and fecal incontinence or the urinary symptom is assigned as a secondary code.

Bladder Control

Urinary Symptoms	**N39.41**	Urge incontinence
	R33.8	Other retention of urine
	R33.9	Retention of urine, unspecified
	R35.0	Frequency of micturition
	R39.14	Feeling of incomplete bladder emptying

Bowel Control

Fecal incontinence	**R15.9**	Full incontinence of feces

Chart continued on next page

ICD-10-CM[1] Diagnosis Codes continued

Other Diagnoses (Bladder Control and Bowel Control)

Device Complications[2,3]	**T85.111A**	Breakdown (mechanical) of implanted electronic neurostimulator of peripheral nerve electrode (lead)[4]
	T85.113A	Breakdown (mechanical) of implanted electronic neurostimulator, generator
	T85.121A	Displacement of implanted electronic neurostimulator of peripheral nerve electrode (lead)[4]
	T85.123A	Displacement of implanted electronic neurostimulator, generator
	T85.191A	Other mechanical complication of implanted electronic neurostimulator of peripheral nerve electrode (lead)[4]
	T85.193A	Other mechanical complication of implanted electronic neurostimulator, generator
	T85.732A	Infection and inflammatory reaction due to implanted electronic neurostimulator of peripheral nerve, electrode (lead)[4]
	T85.734A	Infection and inflammatory reaction due to implanted electronic neurostimulator, generator
	T85.830A	Hemorrhage due to nervous system prosthetic devices, implants and grafts
	T85.840A	Pain due to nervous system prosthetic devices, implants and grafts
	T85.890A	Other specified complication of nervous system prosthetic devices, implants and grafts[5]
Attention to Device[6]	**Z45.42**	Encounter for adjustment and management of neuropacemaker (brain, peripheral nerve, spinal cord)

ICD-10-PCS[7] Procedure Codes

Hospitals use ICD-10-PCS procedure codes for inpatient services.

Lead Implantation[8]	**01HY0MZ**	Insertion of neurostimulator lead into peripheral nerve, open approach
	01HY3MZ	Insertion of neurostimulator lead into peripheral nerve, percutaneous approach
Generator Implantation[9,10,11]	**0JH70BZ**	Insertion single array stimulator generator into back subcutaneous tissue and fascia, open approach
Lead Removal[12]	**01PY0MZ**	Removal of neurostimulator lead from peripheral nerve, open approach
	01PY3MZ	Removal of neurostimulator lead from peripheral nerve, percutaneous approach
Generator Removal[10]	**0JPT0MZ**	Removal of stimulator generator from trunk subcutaneous tissue and fascia, open approach
	0JPT3MZ	Removal of stimulator generator from trunk subcutaneous tissue and fascia, percutaneous approach
Lead Replacement or Generator Replacement	Two codes are required to identify a device replacement: one code for implantation of the new device and one code for removal of the old device.[13]	
Lead Revision[14]	**01WY0MZ**	Revision of neurostimulator lead in peripheral nerve, open approach
	01WY3MZ	Revision of neurostimulator lead in peripheral nerve, percutaneous approach
Generator Revision[15,16]	**0JWT0MZ**	Revision of stimulator generator in trunk subcutaneous tissue and fascia, open approach
	0JWT3MZ	Revision of stimulator generator in trunk subcutaneous tissue and fascia, percutaneous approach

1. Centers for Disease Control and Prevention, National Center for Health Statistics. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). http://www.cdc.gov/nchs/icd/icd10cm.htm. Updated October 1, 2018. Accessed November 7, 2018.
2. When a device complication is the reason for the encounter, the device complication code is sequenced as the primary diagnosis followed by a code for the underlying condition. If the purpose of the encounter is directed toward the underlying condition or the device complication arises after admission, the underlying condition is sequenced as the primary diagnosis followed by the device complication code.
3. Device complication codes ending in "A" are technically defined as "initial encounter" but continue to be assigned for each encounter in which the patient is receiving active treatment for the complication (ICD-10-CM Official Guidelines for Coding and Reporting FY 2019, I.C.19.A).
4. According to ICD-10-CM manual notes (exclusion and inclusion), complications of sacral neurostimulator leads are assigned to codes for "peripheral nerve electrode (lead)" in T85. Although InterStim treats bowel and urinary diagnoses, it is a sacral neurostimulator and is classified as a nervous system device. In particular, do *not* assign codes from T83 for complications of urinary electronic stimulator devices.
5. According to ICD-10-CM manual notes, "other specified complication" includes erosion or breakdown of a subcutaneous device pocket.
6. Code Z45.42 is used as the principal diagnosis when patients are seen for routine device maintenance, such as periodic device checks and programming, as well as routine device replacement. Secondary diagnosis codes are then used for the urinary or bowel symptoms or condition. (ICD-10-CM Official Guidelines for Coding and Reporting FY 2019, I.C.21.C.7).
7. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS). http://www.cms.gov/Medicare/Coding/ICD10/2019-ICD-10-PCS-and-GEMs.html. Updated October 1 , 2018. Accessed November 21, 2018.
8. Approach value 0-Open is used when leads are placed via surgical exposure of the sacral foramen. Approach value 3-Percutaneous is used when leads are placed by needle via puncture or minor incision.
9. Body part value 7-Back is shown because the InterStim generator is typically placed in the subcutaneous tissue of the upper buttock (back). Other body part values are available for sites such as subcutaneous tissue of abdomen.
10. Placement of a neurostimulator generator is shown with the approach value 0-Open because creating the pocket requires surgical dissection and exposure. Removal also usually requires surgical dissection to free the device.
11. Device value B-Stimulator Generator Single Array is shown because the InterStim generator is single array and non-rechargeable (see also the ICD-10-PCS Device Key). Do *not* assign default device value M-Stimulator Generator.
12. Approach value 0-Open is used when leads are removed via dissection or other direct surgical exposure. Approach value 3-Percutaneous is used when leads are removed by puncture or minor incision. Only the ICD-10-PCS codes for surgical removal are displayed. Approach value X-External is also available for removal of leads by simple pull.
13. CMS ICD-10-PCS Reference Manual 2016, p.67.
14. For lead revision, the ICD-10-PCS codes refer to surgical revision of leads within the pelvic space, eg repositioning at the sacral nerve. For revision of the subcutaneous portion of the lead, see Generator Revision.
15. The ICD-10-PCS codes shown can be assigned for opening the pocket for generator revision, as well as reshaping or relocating the pocket while reinserting the *same* generator. However, there are no ICD-10-PCS codes specifically defined for revising the subcutaneous portion of a lead. Because this service usually involves removing and reinserting the generator as well, it can also be represented by the ICD-10-PCS generator revision codes.
16. Approach value X-External is also available for external generator manipulation without opening the pocket, eg to correct a flipped generator.

HCPCS II Device Codes[1] (Non-Medicare)

These codes are utilized by the entity that purchased and supplied the medical device, DME, drug, or supply to the patient. For implantable devices, that is generally the facility. It may also be the physician, most commonly for trial leads placed in the office. For specific Medicare hospital outpatient instructions for medical devices, see Device C-Codes (Medicare) below.

Test Lead[2]	**A4290**	Sacral nerve stimulation test lead, each
Lead[2]	**L8680**	Implantable neurostimulator electrode, each
Pulse Generator[3]	**L8679**	Implantable neurostimulator pulse generator, any type
	L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
Patient Programmer	**L8681**	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only

1. Healthcare Common Procedure Coding System (HCPCS) Level II codes are maintained by the Centers for Medicare and Medicaid Services. http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html. Accessed November 7, 2018.
2. Physicians should not submit code A4290 or code L8680 to Medicare for test leads placed in the office, because the cost of the lead is already valued in the CPT® procedure code. National Correct Coding Initiative (NCCI) edits prohibit use of A4290 with lead implantation 64561 (NCCI Policy Manual 1/1/2019, Chapter VIII, C.35). Further, L8680 is not recognized by Medicare. These codes remain available for use with non-Medicare payers, though physicians should check with the payer for specific coding and billing instructions. Likewise, hospitals and ASCs may be able to submit A4290 or L8680 to non-Medicare payers but should check with the payer for instructions.
3. Effective January 2014, generator code L8686 is not recognized by Medicare. Specifically for billing Medicare, code L8679 is available for physician use, while hospitals typically use C-codes and ASCs generally do not submit HCPCS II codes for devices. For non-Medicare payers, codes L8686 remains available. However, all providers should check with the payer for specific coding and billing instructions.

Device C-Codes (Medicare)[1]

Medicare provides C-codes for hospital use in billing Medicare for medical devices in the outpatient setting. Although other payers may also accept C-codes, regular HCPCS II device codes are generally used for billing non-Medicare payers. Unlike regular HCPCS II device codes, the extension is separately codable using C-codes.

ASCs, however, usually should not assign or report HCPCS II device codes for devices on claims sent to Medicare. Medicare generally does not make a separate payment for devices in the ASC. Instead, payment is "packaged" into the payment for the ASC procedure. ASCs are specifically instructed not to bill HCPCS II device codes to Medicare for devices that are packaged.[2]

Test Lead	**C1897**	Lead, neurostimulator test kit (implantable)
Lead	**C1778**	Lead, neurostimulator (implantable)
Pulse Generator (non-rechargeable)	**C1767**	Generator, neurostimulator (implantable), non-rechargeable
Patient Programmer	**C1787**	Patient programmer, neurostimulator
Extension	**C1883**	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
Lead Introducer	**C1894**	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser

1. Device C-codes are HCPCS Level II codes and are maintained by the Centers for Medicare and Medicaid Services. Healthcare Common Procedure Coding System. http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html. Accessed November 7, 2018.
2. ASCs should report all charges incurred. However, only charges for non-packaged items should be billed as separate line items. For example, the ASC should report its charge for the generator. However, because the generator is a packaged item, the charge should not be reported on its own line. Instead, the ASC should bill a single line for the implantation procedure with a single total charge, including not only the charge associated with the operating room but also the charges for the generator device and all other packaged items. Because of a Medicare requirement to pay the lesser of the ASC rate or the line-item charge, breaking these packaged charges out onto their own lines can result in incorrect payment to the ASC. Centers for Medicare and Medicaid Services. Medicare Claims Processing Manual, Chapter 14—Ambulatory Surgical Centers, section 40. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c14.pdf. Accessed November 7, 2018. See also MLN Matters SE0742 p.9-10: Centers for Medicare and Medicaid Services. MLN Matters Number SE0742 Revised. http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE0742.pdf. Accessed November 7, 2018.

Device Edits (Medicare)[1]

Medicare's procedure-to-device edits require that when certain CPT® procedure codes for device implantation are submitted on a hospital outpatient bill, HCPCS II codes for devices must also be billed. Effective January 2015, the edits are broadly defined and may include any HCPCS II device code with any CPT procedure code used in earlier versions of the edits.[2] Within this context, the HCPCS II device codes shown below are appropriate for the CPT procedure codes and will pass the edits.

CPT Procedure Code	CPT Code Description[3]	HCPCS II Device Codes	HCPCS II Code Description
64561[4,5]	Percutaneous implantation of neurostimulator electrode array, sacral nerve (transforaminal placement) including image guidance if performed	**C1897**	Lead, neurostimulator test kit (implantable)
64581[4,5]	Incision for implantation of neurostimulator electrode array, sacral nerve (transforaminal placement)	**C1778**	Lead, neurostimulator (implantable)
64590[6]	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling	**C1767**	Generator, neurostimulator (implantable) non-rechargeable

1. Centers for Medicare & Medicaid Services. Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems. Final Rule 83 Fed. Reg. 58948-58950 https://www.gpo.gov/fdsys/pkg/FR-2018-11-21/pdf/2018-24243.pdf . Published November 21, 2018.
2. Centers for Medicare & Medicaid Services. Procedure to Device Edits. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Archives.html. Last updated April 10, 2013. Accessed November 7, 2018.
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4. HCPCS II code L8680 will also pass the edits with CPT procedure codes 64561 and 64581, but this code is not shown because it is not otherwise recognized by Medicare.
5. HCPCS II device codes C1778 and C1897 will both pass the edits with CPT procedure codes 64561 and 64581. In practice, however, code 64561 is generally assigned for placement of a trial lead which is represented by C1897. Likewise, in practice, code 64581 is generally assigned for placement of a permanent lead which is represented by C1778.
6. HCPCS II device code L8686 will also pass the edits with CPT procedure code 64590 but this code is not shown because it is not otherwise recognized by Medicare. HCPCS II device code L8679 does not satisfy the edits.

Physician Coding and Payment — January 1, 2019 – December 31, 2019

CPT® Procedure Codes

Physicians use CPT codes for all services. Under Medicare's Resource-Based Relative Value Scale (RBRVS) methodology for physician payment, each CPT code is assigned a point value, known as the relative value unit (RVU), which is then converted to a flat payment amount.

Procedure	CPT Code and Description[1]	Medicare RVUs[2]			Medicare National Average[3]	
		For physician services provided in:[4]				
		Work RVUs	Physician Office–Total[5]	Facility–Total	Physician Office[5]	Facility
Test Stimulation[6] FDA labeling for InterStim Therapy requires a test stimulation procedure. Physicians are allowed to choose either a percutaneous evaluation lead or a tined lead as an initial approach to test stimulation. If the test stimulation using percutaneous lead is inconclusive, then the tined lead may be used for test stimulation. If the test stimulation using a tined lead is inconclusive, test stimulation may be repeated or the lead may be explanted.	**64561** Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance if performed[7,8]	5.44	20.92	8.75	$754	$315
	64581 Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)	12.20	N/A	19.09	N/A	$688
Imaging Guidance[9]	**76000-26** Fluoroscopy, up to one hour - *professional component* [10]	0.30	—	0.44	—	$16
Lead Implantation[6,11]	**64581** Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)[9]	12.20	N/A	19.09	N/A	$688
Generator Implantation or Replacement[6,12]	**64590** Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling	2.45	See note 13	4.64	See note 13	$167
Revision or Removal of Lead or Generator[6,11,12]	**64585** Revision or removal of peripheral neurostimulator electrode array	2.11	7.03	4.14	$253	$149
	64595 Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver	1.78	See note 13	3.63	See note 13	$131

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Physician Coding and Payment — CPT® Procedure Codes *continued*

Procedure	CPT Code and Description[1]	Medicare RVUs[2]			Medicare National Average[3]	
		For physician services provided in:[4]				
		Work RVUs	Physician Office–Total[5]	Facility–Total	Physician Office[5]	Facility
Analysis/ Programming **Note:** In the office, analysis and programming may be furnished by a physician, practitioner with an "incident to" benefit, or auxiliary personnel under the direct supervision of the physician (or other practitioner), with or without support from a manufacturer's representative. The patient or payer should not be billed for services rendered by the manufacturer's representative. Contact your local contractor or payer for interpretation of applicable policies.	**95970** Electronic analysis of implanted neurostimulator pulse generator system (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without reprogramming[14]	0.35	0.54	0.53	$19	$19
	95971 Electronic analysis of implanted neurostimulator pulse generator system (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/ transmitter programming by physician or other qualified health care professional[15,16]	0.78	1.44	1.17	$52	$42
	95972 Electronic analysis of implanted neurostimulator pulse generator system (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/ transmitter programming by physician or other qualified health care professional[15,16]	0.80	1.62	1.19	$58	$43

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Physician Coding and Payment *continued*

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2. Centers for Medicare & Medicaid Services. Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019 Final Rule; 83 Fed. Reg. 59452-60303. https://www.gpo.gov/fdsys/pkg/FR-2018-11-23/pdf/2018-24170.pdf. Published November 23, 2018. The total RVU as shown here is the sum of three components: physician work RVU, practice expense RVU, and malpractice RVU.
3. Medicare national average payment is determined by multiplying the sum of the three RVUs by the conversion factor. The conversion factor for CY 2019 is $36.0391 per 83 Fed. Reg. 59452-60303. https://www.gpo.gov/fdsys/pkg/FR-2018-11-23/pdf/2018-24170.pdf. Published November 23, 2018. See also the January 2019 release of the PFS Relative Value File RVU19A at http:/www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files.html. Released November 6, 2018. Accessed November 21, 2018. Final payment to the physician is adjusted by the Geographic Practice Cost Indices (GPCI). Also note that any applicable coinsurance, deductible, and other amounts that are patient obligations are included in the payment amount shown.
4. The RVUs shown are for the physician's services and payment is made to the physician. However, there are different RVUs and payments depending on the setting in which the physician rendered the service. "Facility" includes physician services rendered in hospitals, ASCs, and SNFs. Physician RVUs and payments are generally lower in the "Facility" setting because the facility is incurring the cost of some of the supplies and other materials. Physician RVUs and payments are generally higher in the "Physician Office" setting because the physician incurs all costs there.
5. "N/A" shown in Physician Office setting indicates that Medicare has not developed RVUs in the office setting because the service is typically performed in a facility (eg, in a hospital). However, if the local contractor determines that it will cover the service in the office, then it is paid using the facility RVUs at the facility rate. Centers for Medicare & Medicaid Services. Details for Title: CMS-1693-F. CY 2019 PFS Final Rule Addenda. Addendum A: Explanation of Addendum B and C. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1693-F.html . Released November 1, 2018. Accessed November 7, 2018.
6. Surgical procedures are subject to a "global period." The global period defines other physician services that are generally considered part of the surgery package. The services are not separately coded, billed, or paid when rendered by the physician who performed the surgery. These services include preoperative visits the day before or the day of the surgery, postoperative visits related to recovery from the surgery for 10 days or 90 days depending on the specific procedure, treatment of complications unless they require a return visit to the operating room, and minor postoperative services such as dressing changes and suture removal.
7. The FDA has approved placing two temporary test stimulation leads during a single bilateral procedure. As defined and as published by the AMA (*CPT Assistant*, December 2008, p.8-9), code 64561 represents a single lead, and when more than one lead is placed, each is coded separately. Further, Medicare permits the use of bilateral modifier -50 with code 64561. To show placement of two test leads, submit 64561-50 with 1 unit. Centers for Medicare and Medicaid Services. Transmittal 1421, CR 8853. http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1421OTN.pdf. Released August 15, 2014. Accessed November 7, 2018. See also Medicare Claims Processing Manual, Chapter 12—Physicians/Nonphysician Practitioners, section 40.7.B. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf. Accessed November 7, 2018. See also NCCI Policy Manual 1/1/2019, Chapter I,V.3.a.ii. Note that Medicare's Medically Unlikely Edits allow 1 unit for code 64561 on the same date of service.
8. NCCI policy and edits do not allow HCPCS II test lead code A4290 to be submitted with procedure code 64561, because code 64561 is already valued to include the test lead (NCCI Policy Manual 1/1/Chapter VIII, C.35).
9. Because the definition of code 64561 includes image guidance, use of fluoroscopy is inherent to 64561 and cannot be coded separately. However, fluoroscopy can be coded separately with 64581. (See also *CPT Assistant*, September 2014, p.5.). Similarly, NCCI edits prohibit use of fluoroscopy codes with 64561, but there are no edits with 64581.
10. RVUs exist for this code in the office setting. However, they are not displayed because the professional component –26 is customarily provided in the facility setting.
11. When an existing lead is removed and replaced by a new lead, only the lead implantation code 64581 may be assigned. For lead replacement, NCCI edits do not allow removal of the existing lead to be coded separately with implantation of the new lead.
12. When an existing generator is removed and replaced by a new generator, only the generator replacement code 64590 may be assigned. NCCI edits do not allow removal of the existing generator to be coded separately. Also note that, according to NCCI policy, use of the CPT code for generator "insertion or replacement" requires placement of a new generator. When the *same* generator is removed and then re-inserted, the "revision" code is used (see NCCI Policy Manual 1/1/2019, Chapter VIII, C.16).
13. RVUs exist for this code in the office setting. However, the RVUs are not displayed because generator implantation and replacement customarily take place in the facility setting.
14. Code 95970 is used for electronic analysis (interrogation) of the implanted neurostimulator without programming. Per CPT manual instructions, code 95970 is integral to lead and/or generator implantation and cannot be assigned separately. NCCI edits also prohibit coding 95970 separately with generator implantation. In addition, test stimulation during an implantation procedure is considered integral and code 95970 cannot be assigned to represent this.
15. According to CPT manual instructions, "simple" programming involves changes to three or fewer parameters and "complex" programming involves changes to four or more parameters.
16. According to CPT manual instructions, programming codes may be assigned as long as iterative adjustments to the parameters are made and assessed, regardless of whether the final settings are ultimately changed.

Hospital Outpatient Coding and Payment — Effective January 1, 2019 – December 31, 2019

CPT® Procedure Codes

Hospitals use CPT codes for outpatient services. Under Medicare's APC methodology for hospital outpatient payment, each CPT code is assigned to one of approximately 740 ambulatory payment classes. Each APC has a relative weight that is then converted to a flat payment amount. Multiple APCs can sometimes be assigned for each encounter, depending on the number of procedures coded and whether any of the procedure codes map to a Comprehensive APC.

For 2019, there are 63 APCs which are designated as Comprehensive APCs (C-APCs). Each CPT procedure code assigned to one of these C-APCs is considered a primary service, and all other procedures and services coded on the bill are considered adjunctive to delivery of the primary service. This results in a single APC payment and a single beneficiary copayment for the entire outpatient encounter, based solely on the primary service. Separate payment is not made for any of the other adjunctive services. Instead, the payment level for the C-APC is calculated to include the costs of the other adjunctive services, which are packaged into the payment for the primary service.

When more than one primary service is coded for the same outpatient encounter, the codes are ranked according to a fixed hierarchy. The C-APC is then assigned according to the highest ranked code. In some special circumstances, the combination of two primary services leads to a "complexity adjustment" in which the entire encounter is re-mapped to another higher-level APC. However, there are no complexity adjustments for InterStim therapy.

As shown on the tables below, InterStim therapy is subject to C-APCs specifically for implantation of the leads, and implantation/replacement of the generator. C-APCs are identified by status indicator J1.

Procedure	CPT Code and Description[1]	APC[2]	APC Title[2]	SI[2,3]	Relative Weight[2]	Medicare National Average[2,4]
Test Stimulation FDA labeling for InterStim Therapy requires a test stimulation procedure. Physicians are allowed to choose either a percutaneous evaluation lead or a tined lead as an initial approach to test stimulation. If the test stimulation using percutaneous lead is inconclusive, then the tined lead may be used for test stimulation. If the test stimulation using a tined lead is inconclusive, test stimulation may be repeated or the lead may be explanted.	**64561** Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance if performed[5]	5462	Level 2 Neurostimulator and Related Procedures	J1	75.2237	$5,980
	64581 Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)	5462	Level 2 Neurostimulator and Related Procedures	J1	75.2237	$5,980
	Under comprehensive APCs for 2019, when code 64561 is assigned with bilateral modifier-50 or is coded twice during the same encounter to show that two leads were placed, this does *not* qualify for a complexity adjustment. Although two leads were placed, the entire encounter remains under APC 5462.					
Imaging Guidance[6]	**76000** Fluoroscopy, up to one hour	5523	Level 3 Imaging Without Contrast	S	2.9005	$231
Lead Implantation[7,8]	**64581** Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)	5462	Level 2 Neurostimulator and Related Procedures	J1	75.2237	$5,980
Generator Implantation or Replacement[8,9]	**64590** Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling	5463	Level 3 Neurostimulator and Related Procedures	J1	235.3398	$18,707

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Hospital Outpatient Coding and Payment — CPT® Procedure Codes *continued*

Procedure	CPT Code and Description[1]	APC[2]	APC Title[2]	SI[2,3]	Relative Weight[2]	Medicare National Average[2,4]
Revision or Removal of Lead or Generator[7,9]	**64585** Revision or removal of peripheral neurostimulator electrode array	5461	Level 1 Neurostimulator and Related Procedures	Q2	36.2285	$2,880
	64595 Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver	5461	Level 1 Neurostimulator and Related Procedures	Q2	36.2285	$2,880
Analysis/ Programming **Note:** In the hospital, analysis and programming may be furnished by a physician or nurse with or without support from a manufacturer's representative. Neither the payer or the patient should be billed for services rendered by the manufacturer's representative. Contact the local contractor or payer for interpretation of applicable policies.	**95970** Electronic analysis of implanted neurostimulator pulse generator system (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without reprogramming[10]	5734	Level 4 Minor Procedures	Q1	1.3396	$106
	95971 Electronic analysis of implanted neurostimulator pulse generator system (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional[11,12]	5742	Level 2 Electronic Analysis of Devices	S	1.4787	$118
	95972 Electronic analysis of implanted neurostimulator pulse generator system (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional[11,12]	5742	Level 2 Electronic Analysis of Devices	S	1.4787	$118

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Hospital Outpatient Coding and Payment *continued*

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2. Centers for Medicare & Medicaid Services. Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems. Final Rule. 83 Fed. Reg. 58818-59179. https://www.gpo.gov/fdsys/pkg/FR-2018-11-21/pdf/2018-24243.pdf Published November 21, 2018. Correction Notice 83 Fed. Reg. 67083-67094 https://www.gpo.gov/fdsys/pkg/FR-2018-12-28/pdf/2018-28348.pdf. Published December 28, 2018.
3. Status Indicator (SI) shows how a code is handled for payment purposes. J1 = paid under comprehensive APC, single payment based on primary service without separate payment for other adjunctive services; S = always paid at 100% of rate; T = paid at 50% of rate when billed with another higher-weighted T procedure; Q1 = STV packaged codes, not paid separately when billed with an S, T, or V procedure, Q2 = T packaged codes, not paid separately when billed with a T procedure.
4. Medicare national average payment is determined by multiplying the APC weight by the conversion factor. The conversion factor for 2019 is $79.490. The conversion factor of $79.490 assumes that hospitals meet reporting requirements of the Hospital Outpatient Quality Reporting Program. Centers for Medicare & Medicaid Services. Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems. Final Rule. 83 Fed. Reg. 58818-59179. https://www.gpo.gov/fdsys/pkg/FR-2018-11-21/pdf/2018-24243.pdf Published November 21, 2018. Correction Notice 83 Fed. Reg. 67083-67094 https://www.gpo.gov/fdsys/pkg/FR-2018-12-28/pdf/2018-28348.pdf. Published December 28, 2018. Payment is adjusted by the wage index for each hospital's specific geographic locality, so payment will vary from the national average Medicare payment levels displayed. Also note that any applicable coinsurance, deductible, and other amounts that are patient obligations are included in the national average payment amount shown.
5. The FDA has approved placing two temporary test stimulation leads during a single bilateral procedure. As defined and as published by the AMA (*CPT Assistant,* December 2008, p.8-9), code 64561 represents a single lead, and when more than one lead is placed, each is coded separately. Further, Medicare permits the use of bilateral modifier -50 with code 64561. To show placement of two test leads, submit 64561-50 with 1 unit. Centers for Medicare and Medicaid Services. Transmittal 1421, CR 8853. http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1421OTN.pdf. Released August 15, 2014. Accessed November 7, 2018. See also Medicare Claims Processing Manual, Chapter 4—Part B Hospital, sections 20.6 and 20.6.2. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf. Accessed November 7, 2018. See also NCCI Policy Manual 1/1/2019, Chapter I,V.3.a.ii. Note that Medicare's Medically Unlikely Edits allow 1 unit for code 64561 on the same date of service.
6. Because the definition of code 64561 includes image guidance, use of fluoroscopy is inherent to 64561 and cannot be coded separately. However, fluoroscopy can be coded separately with 64581. (See also *CPT Assistant*, September 2014, p.5.) Similarly, NCCI edits prohibit use of fluoroscopy codes with 64561, but there are no edits with 64581.
7. When an existing lead is removed and replaced by a new lead, only the lead implantation code 64581 may be assigned. For lead replacement, NCCI edits do not allow removal of the existing lead to be coded separately with implantation of the new lead.
8. When generator implantation is coded and billed together with lead implantation, ie. 64590 plus 64581, the entire encounter continues to map to APC 5463. Because this is a C-APC and no complexity adjustment applies, there is no additional payment for the lead.
9. When an existing generator is removed and replaced by a new generator, only the generator replacement code 64590 may be assigned. NCCI edits do not allow removal of the existing generator to be coded separately. Also note that, according to NCCI policy, use of the CPT code for generator "insertion or replacement" requires placement of a new generator. When the *same* generator is removed and then re-inserted, the "revision" code is used (see NCCI Policy Manual 1/1/2019, Chapter VIII, C.16).
10. Code 95970 is used for electronic analysis (interrogation) of the implanted neurostimulator without programming. Per CPT manual instructions, code 95970 is integral to lead and/or generator implantation and cannot be assigned separately. NCCI edits also prohibit coding 95970 separately with generator implantation. In addition, test stimulation during an implantation procedure is considered integral and code 95970 cannot be assigned to represent this.
11. According to CPT manual instructions, "simple" programming involves changes to three or fewer parameters and "complex" programming involves changes to four or more parameters.
12. According to CPT manual instructions, programming codes may be assigned as long as iterative adjustments to the parameters are made and assessed, regardless of whether the final settings are ultimately changed.

Hospital Inpatient Coding and Payment — Effective October 1, 2018 – September 30, 2019

MS-DRG Assignments

Under Medicare's MS-DRG methodology for hospital inpatient payment, each inpatient stay is assigned to one of about 755 diagnosis-related groups, based on the ICD-10-CM codes assigned to the diagnoses and ICD-10-PCS codes assigned to the procedures. Each MS-DRG has a relative weight that is then converted to a flat payment amount. Only one MS-DRG is assigned for each inpatient stay, regardless of the number of procedures performed. The MS-DRGs shown are those typically assigned to the following scenarios. For InterStim, DRG assignment varies depending on the diagnosis and the specific procedures performed.

Procedure	Scenario		MS-DRG[1]	MS-DRG Title[1,2]	Relative Weight[1]	Medicare National Average[3]
Implantation or Replacement	Fecal incontinence[4]	Whole system (generator plus leads) *or* Lead only *or* Generator only	981	Extensive OR Procedure Unrelated to Principal Diagnosis W MCC	4.3705	$26,684
			982	Extensive OR Procedure Unrelated to Principal Diagnosis W CC	2.4529	$14,976
			983	Extensive OR Procedure Unrelated to Principal Diagnosis W/O CC/MCC	1.5691	$9,580
	Urinary symptoms[5]	Whole system (generator plus leads) *or* Lead only	673	Other Kidney and Urinary Tract Procedures W MCC	3.5773	$21,841
			674	Other Kidney and Urinary Tract Procedures W CC	2.3121	$14,117
			675	Other Kidney and Urinary Tract Procedures W/O CC/MCC	1.6253	$9,923
		Generator only	981	Extensive OR Procedure Unrelated to Principal Diagnosis W MCC	4.3705	$26,684
			982	Extensive OR Procedure Unrelated to Principal Diagnosis W CC	2.4529	$14,976
			983	Extensive OR Procedure Unrelated to Principal Diagnosis W CC	1.5691	$9,580
Removal (without Replacement)[6,7]	Whole system removal (generator plus leads)[8] *or* Lead only removal		040	Peripheral/Cranial Nerve and Other Nervous System Procedures W MCC	3.9282	$23,984
			041	Peripheral/Cranial Nerve and Other Nervous System Procedures W MCC or Peripheral Neurostimulators	2.3584	$14,399
			042	Peripheral/Cranial Nerve and Other Nervous System Procedures W/O CC/MCC	1.8715	$11,426
	Generator only removal		These codes are not considered a "significant procedure" for the purpose of DRG assignment. A non-surgical (ie, medical) DRG is assigned to the stay according to the principal diagnosis.			

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Hospital Inpatient Coding and Payment — MS-DRG Assignments *continued*

Procedure	Scenario	MS-DRG[1]	MS-DRG Title[1,2]	Relative Weight[1]	Medicare National Average[3]
Revision[6,7]	Lead revision[9]	040	Peripheral/Cranial Nerve and Other Nervous System Procedures W MCC	3.9282	$23,984
		041	Peripheral/Cranial Nerve and Other Nervous System Procedures W CC or Peripheral Neurostimulator	2.3584	$14,399
		042	Peripheral/Cranial Nerve and Other Nervous System Procedures W/O CC/MCC	1.8715	$11,426
	Generator revision	These codes are not considered "significant procedures" for the purpose of DRG assignment. A non-surgical (ie, medical) DRG is assigned to the stay according to the principal diagnosis.			

1. Centers for Medicare & Medicaid Services. Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Changes and FY2019 Rates Final Rule, 83 Fed. Reg. 41144-41784 https://www.gpo.gov/fdsys/pkg/FR-2018-08-17/pdf/2018-16766.pdf. Published August 17, 2018. Correction Notice 83 Fed. Reg. 49836-49856 https://www.gpo.gov/fdsys/pkg/FR-2018-10-03/pdf/2018-21500.pdf. Published October 3, 2018.
2. W MCC in MS-DRG titles refers to secondary diagnosis codes that are designated as major complications or comorbidities. MS-DRGs W MCC have at least one major secondary complication or comorbidity. Similarly, W CC in MS-DRG titles refers to secondary diagnosis codes designated as other (non-major) complications or comorbidities, and MS-DRGs W CC have at least one other (non-major) secondary complication or comorbidity. MS-DRGs W/O CC/MCC have no secondary diagnoses that are designated as complications or comorbidities, major or otherwise. Note that some secondary diagnoses are only designated as CCs or MCCs when the conditions were present on admission, and do not count as CCs or MCCs when the conditions were acquired in the hospital during the stay.
3. Payment is based on the average standardized operating amount ($5,646.80) plus the capital standard amount ($459.51). Centers for Medicare & Medicaid Services. Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Changes and FY2019 Rates Final Rule 83 Fed. Reg. 41740-41741 https://www.gpo.gov/fdsys/pkg/FR-2018-08-17/pdf/2018-16766.pdf. Published August 17, 2018. Correction Notice 83 Fed. Reg. 49846 https://www.gpo.gov/fdsys/pkg/FR-2018-10-03/pdf/2018-21500.pdf. Published October 3, 2018. Tables 1A-1D. The payment rate shown is the standardized amount for facilities with a wage index greater than one. The average standard amounts shown also assume facilities receive the full quality update. The payment will also be adjusted by the Wage Index for specific geographic locality. Therefore, payment for a specific hospital will vary from the stated Medicare national average payment levels shown. Also note that any applicable coinsurance, deductible, and other amounts that are patient obligations are included in the national average payment amount shown.
4. For InterStim for Bowel Control, DRG logic designates the fecal incontinence code as a digestive system diagnosis while the codes for lead implantation and generator implantation are designated as nervous system procedures. The result is that the "mismatch" MS-DRGs 981, 982 and 983 are assigned. These DRGs are valid and payable.
5. For InterStim for Bladder Control, DRG logic "matches" the urinary symptom diagnosis codes with the lead implantation code but not with the generator implantation code. This makes the lead code the "driver" in DRG assignment, so the same MS-DRGs are assigned based on the lead code regardless of whether the generator is also implanted. However, when the generator is implanted by itself, the "mismatch" MS-DRGs 981, 982 and 983 are assigned. These DRGs are valid and payable.
6. Procedures involving device removal without replacement and device revisions are typically performed as an outpatient. They are shown here for the occasional scenario where removal or revision takes places as an inpatient .
7. Neurostimulators may be removed for diagnoses involving device complications. Because neurostimulator device complications are designated as nervous system diagnoses and neurostimulators are classified as nervous system devices, removal and revision procedures are assigned to Nervous System MS-DRGs in these scenarios.
8. When the generator and leads are removed together, the lead removal code is the "driver "and groups to the DRGs shown.
9. For lead revision, the DRGs reflect surgical revision of the portion of the lead within the pelvic space, eg, repositioning a displaced lead at the sacral nerve.

ASC Coding and Payment — Effective January 1, 2019 – December 31, 2019

CPT® Procedure Codes

ASCs use CPT codes for their services. Medicare payment for procedures performed in an ambulatory surgery center is generally based on Medicare's ambulatory patient classification (APC) methodology for hospital outpatient payment. However, Comprehensive APCs (C-APCs) are used only for hospital outpatient services and are not applied to procedures performed in ASCs. Alternately, payment for some CPT codes is based on the physician fee schedule payment, particularly for procedures commonly performed in the physician office.

Each CPT code designated as a covered procedure in an ASC is assigned a comparable relative weight as under the hospital outpatient APC system. This is then converted to a flat payment amount using a conversion factor unique to ASCs. Multiple procedures can be paid for each claim. Certain ancillary services, such as imaging, are also covered when they are integral to covered surgical procedures, although they may not be separately payable. In general, there is no separate payment for devices; their payment is packaged into the payment for the procedure.

Procedure	CPT Code and Description[1]	Payment Indicator[2,3,4]	Multiple Procedure Discounting[5]	Relative Weight[2,4]	Medicare National Average[2,4,6]
Test Stimulation FDA labeling for InterStim Therapy requires a test stimulation procedure. Physicians are allowed to choose either a percutaneous evaluation lead or a tined lead as an initial approach to test stimulation. If the test stimulation using percutaneous lead is inconclusive, then the tined lead may be used for test stimulation. If the test stimulation using a tined lead is inconclusive, test stimulation may be repeated or the lead may be explanted.	**64561** Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance if performed[7]	J8	N	98.5827	$4,587
	64581 Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)	J8	N	103.6465	$4,823
Imaging Guidance[8]	**76000** Fluoroscopy, up to one hour	Z3	-	-	$32
Lead Implantation[9]	**64581** Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)	J8	N	103.6465	$4,823
Generator Implantation or Replacement[10]	**64590** Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling	J8	N	364.4284	$16,958
Revision or Removal of Lead or Generator[9,10]	**64585** Revision or removal of peripheral neurostimulator electrode array	A2	N	31.8811	$1,483
	64595 Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver	J8	N	42.3446	$1,970

ASC Coding and Payment *continued*

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2. Centers for Medicare & Medicaid Services. Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems. Final Rule. 83 Fed. Reg. 58818-59179. https://www.gpo.gov/fdsys/pkg/FR-2018-11-21/pdf/2018-24243.pdf Published November 21, 2018. Correction Notice 83 Fed. Reg. 67083-67094 https://www.gpo.gov/fdsys/pkg/FR-2018-12-28/pdf/2018-28348.pdf. Published December 28, 2018.
3. The Payment Indicator shows how a code is handled for payment purposes. J8 = device-intensive procedure, payment amount adjusted to incorporate device cost; A2 = surgical procedure, payment based on hospital outpatient rate adjusted for ASC; Z3 = radiology service, paid separately when provided integral to an ASC surgical procedure.
4. Medicare national average payment is determined by multiplying the relative weight by the ASC conversion factor. The 2018 ASC conversion factor is $45.639. The conversion factor of $45.639 assumes the ASC meets quality reporting requirements. Centers for Medicare & Medicaid Services. Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems. Final Rule. 83 Fed. Reg. 58818-59179. https://www.gpo.gov/fdsys/pkg/FR-2018-11-21/pdf/2018-24243.pdf Published November 21, 2018. Correction Notice 83 Fed. Reg. 67083-67094 https://www.gpo.gov/fdsys/pkg/FR-2018-12-28/pdf/2018-28348.pdf. Published December 28, 2018. Payment is adjusted by the wage index for each ASC's specific geographic locality, so payment will vary from the stated national average Medicare payment levels displayed. Also note that any applicable coinsurance, deductible, and other amounts that are patient obligations are included in the national average payment amount shown.
5. When multiple procedures are coded and billed, payment is usually made at 100% of the rate for the first procedures and 50% of the rate for the second and all subsequent procedures. Procedures subject to discounting are marked "Y." However, procedures marked "N" are not subject to this discounting and are paid at 100% of the rate regardless of whether they are submitted with other procedures.
6. For Medicare billing, ASCs use a CMS-1500 form.
7. The FDA has approved placing two temporary test stimulation leads during a single bilateral procedure. As defined and as published by the AMA (*CPT Assistant,* December 2008, p.8-9), code 64561 represents a single lead and when more than one lead is placed, each is coded separately. However, Medicare does not recognize the use of bilateral modifier -50 for payment in the ASC and instructs that bilateral procedures should either be reported with the CPT procedure code repeated on two separate lines or reported on a single line with units of "2". Centers for Medicare and Medicaid Services. Medicare Claims Processing Manual, Chapter 14—Ambulatory Surgery Centers, section 40.5: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c14.pdf. Accessed November 7, 2018. Medicare's Medically Unlikely Edits allow 1 unit for code 64561 on the same date of service but this value is doubled for ASCs. Centers for Medicare and Medicaid Services. Transmittal 1421, CR 8853, 4-General Processing Instructions. http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1421OTN.pdf. Released August 15, 2014. Accessed November 7, 2018. For billing to non-Medicare payers, contact the payer for instructions.
8. Because the definition of code 64561 includes image guidance, use of fluoroscopy is inherent to 64561 and cannot be coded separately. However, fluoroscopy can be coded separately with 64581. (See also *CPT Assistant*, September 2014, p.5.) Similarly, NCCI edits prohibit use of fluoroscopy codes with 64561, but there are no edits with 64581.
9. When an existing lead is removed and replaced by a new lead, only the lead implantation code 64581 may be assigned. For lead replacement, NCCI edits do not allow removal of the existing lead to be coded separately with implantation of the new lead.
10. When an existing generator is removed and replaced by a new generator, only the generator replacement code 64590 may be assigned. NCCI edits do not allow removal of the existing generator to be coded separately. Also note that, according to NCCI policy, use of the CPT code for generator "insertion or replacement" requires placement of a new generator. When the *same* generator is removed and then re-inserted, the "revision" code is used (see NCCI Policy Manual 1/1/2019, Chapter VIII, C.16).

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Indications for Use:

Sacral Neuromodulation delivered by the InterStim™ system for Urinary Control is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

The following Warning applies only to Sacral Neuromodulation for Urinary Control:

> **Warning**: This therapy is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture.

Sacral Neuromodulation delivered by the InterStim™ system for Bowel Control is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.

Contraindications for Urinary Control and for Bowel Control: Diathermy. Patients who have not demonstrated an appropriate response to test stimulation or are unable to operate the neurostimulator.

Warnings/Precautions/Adverse Events:

For Urinary Control: Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 16; or for patients with neurological disease origins.

For Bowel Control: Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 18; or for patients with progressive, systemic neurological diseases.

For Urinary Control and for Bowel Control: The system may be affected by or adversely affect cardiac devices, electrocautery, defibrillators, ultrasonic equipment, radiation therapy, MRI, theft detectors/ screening devices. Adverse events include pain at the implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations, including jolting or shock sensations. Patients should be assessed preoperatively for the risk of increased bleeding. For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com. Product technical manual must be reviewed prior to use for detailed disclosure.

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