Sacral and Tibial Nerve Stimulation For Urinary Voiding Dysfunction and Fecal Incontinence

Policy Number: 2016M0065B  Effective Date: September 1, 2016

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee's specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This policy provides information on sacral nerve neuromodulation (SNM) treatment, also known as sacral nerve stimulation (SNS), an alternative treatment modality for patients with fecal or urinary incontinence (UI) who have failed behavioral and/or pharmacologic therapies.

The SNM device (Medtronic InterStim® Sacral Nerve Stimulation system) consists of an implantable pulse generator that delivers controlled electrical impulses. This pulse generator (implanted in the abdomen) is attached to wire leads (tunneled below the skin) that connect to the sacral nerves, most commonly the S3 nerve root. Two external components of the system help control the electrical stimulation. A control magnet is kept by the patient and can be used to turn the device on or off. A console programmer is kept by the physician and used to adjust the settings of the pulse generator.

This therapy consists of two phases, the test stimulation phase and implantation. The goal of sacral nerve neuromodulation treatment is to restore voluntary urination/defecation in patients with urinary or fecal voiding dysfunction.

This policy does not address pelvic floor stimulation. For pelvic floor stimulation information refer to the medical policy “Pelvic Floor Electrical Stimulation for the Treatment of UI”, 2013M0028A.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

I. URINARY INCONTINENCE (UI) AND NON-OBSTRUCTIVE RETENTION

A. SACRAL NERVE NEUROMODULATION

A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered MEDICALLY NECESSARY in patients who meet all of the following criteria:

1. There is a diagnosis of at least one of the following:
   a. Urinary urge incontinence
   b. Urinary urgency-frequency syndrome
   c. Non-obstructive urinary retention

2. The patient has experienced urge UI or symptoms of urge-frequency for at least 12 months and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member's ability to participate in daily activities)

3. There is documented failure or intolerance to at least two conventional conservative therapies:
   a. Behavioral training such as bladder training or biofeedback
   b. Prompted voiding
   c. Pelvic muscle exercise training (e.g., kegel exercises)
   d. Pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy

4. The patient is an appropriate surgical candidate.

5. Incontinence is not related to a neurologic condition.
Permanent implantation of a sacral nerve neuromodulation device may be considered medically necessary in patients who meet all of the following criteria:

1. All of the criteria in A (1-4) above are met.
2. A trial stimulation period demonstrates at least 50% improvement in symptoms (reduction in urinary retention, urge incontinence, and/or urge frequency) over a period of at least 1 week.

Other urinary/voiding applications of sacral nerve neuromodulation are considered INVESTIGATIONAL AND/OR EXPERIMENTAL, including but not limited to treatment of stress incontinence or urge incontinence due to a neurologic condition, e.g., detrusor hyperreflexia, multiple sclerosis, spinal cord injury, or other types of chronic voiding dysfunction.

B. PERCUTANEOUS TIBIAL NERVE STIMULATION (PTNS)

PTNS, also known as posterior tibial nerve stimulation, is considered MEDICALLY NECESSARY in patients with moderate to severe urinary dysfunction and overactive bladder syndrome when the following criteria are met:

1. An evaluation by an appropriate specialist, usually a urologist or urogynecologist, has been performed and the specialist has determined that the patient is a candidate for PTNS; AND
2. The Patient has had urinary dysfunction for at least 12 months and the condition has resulted in significant disability (i.e., the urinary urgency, frequency and or the severity of symptoms are limiting the member’s ability to participate activities of daily living); AND
3. The patient has tried various medications (e.g., alpha blockers and cholinergics, and antibiotics for urinary tract infections) that have failed or are not well-tolerated.
4. The patient has documented a willingness to attend in-office treatment sessions, to comply with the behavioral therapies, and to continue to keep voiding diaries including documentation of behavioral therapy compliance; AND
5. Treatment will consist of an initial course of one 30-minute session per week for 12 weeks.

Treatments for relapse shall only be allowed for those patients who achieve a >50% decrease in OBS symptoms with the initial treatment and then relapse.

II. FECAL INCONTINENCE

A. SACRAL NERVE NEUROMODULATION

A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered MEDICALLY NECESSARY in patients who meet all of the following criteria:

1. There is a diagnosis of chronic fecal incontinence of greater than 2 incontinent episodes on average per week with duration greater than 6 months or for more than 12 months after vaginal childbirth.
2. There is documented failure, contraindication, or intolerance to conventional conservative therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, performed more than 12 months.
3. Sphincter surgery is either not indicated or is contraindicated.
4. Absence of a significant anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae) or chronic inflammatory bowel disease involving the anus.

5. Incontinence is not secondary to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

**Permanent implantation** of a sacral nerve neuromodulation device may be considered **MEDICALLY NECESSARY** in patients who meet all of the following criteria:

1. All of the criteria in II- A (1-5) above are met.
2. A trial stimulation period demonstrates at least 50% sustained improvement in symptoms over a period of at least 1 week.

Sacral nerve neuromodulation is considered **INVESTIGATIONAL AND/OR EXPERIMENTAL** for fecal incontinence that may be related to:

1. Rectal surgery for conditions other than cancer
2. Chronic pelvic pain
3. Sequelae of pelvic radiation
4. Active anal abscesses and fistulae
5. Chronic inflammatory bowel disease (IBD)
6. Peripheral neuropathy
7. Complete spinal cord injury (no motor or sensory function at sacral segments S4-S5)
8. Chronic constipation

Sacral nerve neuromodulation is considered **INVESTIGATIONAL AND/OR EXPERIMENTAL** in the treatment of fecal incontinence in children. There is insufficient evidence to recommend the widespread clinical adoption of the InterStim Therapy System for pediatric patients less than 18 years of age with fecal incontinence due to the lack of evidence regarding its safety and clinical value.

**B. PERCUTANEOUS TIBIAL NERVE STIMULATION (PTNS)**

Sacral nerve neuromodulation is considered **INVESTIGATIONAL AND/OR EXPERIMENTAL** for fecal incontinence. PTNS is not cleared by the FDA for treating fecal incontinence; however, the treatment has been proposed for this purpose.

### Clinical Considerations:

Prior to the implantation of a permanent SNS system, patients are screened for potential therapeutic benefit by undergoing a trial in which a temporary electrode is percutaneously introduced into the left or right sacral nerve foramen and an external device provides continuous stimulation. The length of the screening trial varies. The patient must demonstrate a positive therapeutic response to qualify as a candidate for permanent implantation.

### Complications/Adverse Events:

- Device-related pain, discomfort, and/or infection at the implantation site.
- Technical complications such as early displacement of the electrode (also called lead migration) that
required repositioning and revision of the permanent electrode due to functional failure.

**Contraindications:**

- According to the manufacturer, the safety and effectiveness of the InterStim Therapy system has not been established for bilateral stimulation; use during pregnancy and delivery; on an unborn fetus; pediatric use under the age of 18 years; or for patients with progressive, systemic neurological diseases.
- The InterStim Therapy System should not be used in patients who are undergoing any type of diathermy, a heat treatment used for sore or stiff muscles, including shortwave, microwave, or therapeutic ultrasound diathermy.
- The procedure is not recommended in patients with recent rectal surgery; external rectal prolapsed, chronic bowel disease; or in patients with urologic or gynecologic malignancies.
- InterStim Therapy System may be affected by or adversely affect cardiac devices, electrocautery, defibrillators, ultrasonic equipment, radiation therapy, magnetic resonance imaging, theft detectors, or screening devices.

**BACKGROUND:**

**Urinary Incontinence**

Urinary voiding dysfunction, also referred to as urinary incontinence (UI), is generally defined as the inability to control urination. The prevalence of UI for men and women between the ages of 15 and 64 years has been reported to be 25% to 55%, although it approaches approximately 60% among nursing home residents of both sexes. Several studies report that women are affected twice as often as men younger than 80 years of age, and after 80 years of age, the prevalence rate is similar. Urinary voiding disorders are generally divided into five types of incontinence, depending on the pathophysiology involved: urge, overflow, stress, mixed, and functional. In urge incontinence, urine leakage results from the inability to inhibit the voiding reflex consciously. A subtype of this condition, urgency-frequency syndrome, is characterized by uncontrollable urgency without urine loss and the need to void more than 7 times per day. Overflow incontinence, or urinary retention, is a condition in which the bladder overfills without causing the sensation of the need to urinate. Stress incontinence is characterized by the leakage of urine during physical activities that increase pressure on the bladder. Mixed incontinence refers to a combination of urge and stress incontinence. Functional incontinence refers to the inability of a person to reach the bathroom due to chronic impairment of physical or mental functioning. Treatment options for urinary voiding disorders include behavioral strategies, pharmacological interventions, temporary electrical stimulation, and reconstructive surgery. Usually, the less invasive first-tier behavioral and pharmacological interventions are advised and are often combined with temporary electrical stimulation before irreversible, reconstructive surgery is considered as a treatment choice.

**Fecal Incontinence**

Fecal incontinence is the inability to control the release of fecal matter, which can cause significant embarrassment, social isolation, and reduced quality of life (QOL). The overall prevalence of fecal incontinence ranges from 1% to 7% in otherwise healthy individuals, and up to 10% in the elderly. The prevalence of fecal incontinence is disproportionally higher in women, in the elderly, and in nursing home residents. There are many causes of fecal incontinence including anal sphincter trauma, local rectal pathology, neurological disorders, congenital anomalies, psychological chronic soiling, and the normal aging
process. There are several conservative and surgical options for fecal incontinence. First-line treatments generally include nonsurgical approaches, such as biofeedback therapy, use of absorbent products, lifestyle and dietary modifications, bowel habit interventions, anal plugs, pelvic floor muscle training, rectal irrigation, and drug therapy. If first-line treatment fails, surgical management generally includes repair of the anal sphincter, use of injectible bulking agents, development of an artificial bowel sphincter, stoma, antegrade continence edema, and percutaneous tibial nerve stimulation.

Sacral Nerve Neuromodulation
Sacral nerve stimulation, using the Medtronic InterStim Therapy System, is the application of a mild electrical pulse to the sacral nerves through a surgically implanted neuromodulation system to treat urinary/fecal incontinence. The electrical pulses modulate the sacral nerves that influence the functioning of the bladder, bowel, urinary, and anal sphincters, and the pelvic floor muscles. Stimulation of the sacral nerves (S2-S4) generally causes a lifting and tightening of the anus, and contraction of the external sphincter. Implantation of the InterStim neurostimulator is a two-phase process. The first phase consists of a trial period to determine if a patient is likely to achieve optimal benefit from long-term implantation. The length of the screening trial varies. The patient must demonstrate a positive therapeutic response to qualify as a candidate for permanent implantation. If the patient experiences a decline in bowel accidents by at least half the number of incontinence episodes in a typical week, the patient may benefit from the InterStim Therapy System. The second phase involves the permanent implantation of the neurostimulator, which requires a surgical procedure under general or local anesthesia, typically performed by a gastroenterologist or colorectal surgeon on an outpatient basis. The sacral nerve neurostimulator (InterStim device) is inserted under the skin through a small incision in the upper buttock, and placed in a subcutaneous pocket. The long-term lead is implanted in the tailbone and modulates a sacral nerve adjacent to the lead. For the purposes of this assessment, sacral nerve stimulation is intended as second-line therapy in children with chronic fecal incontinence who have not responded favorably to medical therapy, who are not appropriate candidates for conservative treatments, or who may require invasive surgery.

Percutaneous tibial nerve stimulation therapy (PTNS)
PTNS is a minimally invasive neuromodulation treatment designed to provide sacral nerve stimulation through percutaneous electrical stimulation of the posterior tibial nerve. Sacral neuromodulation involves stimulation of the sacral nerve plexus which regulates bladder and pelvic floor function. Stimulating the posterior tibial nerve with PTNS is purported to improve voiding function and control. While the posterior tibial nerve is located near the ankle, it is derived from the lumbarsacral nerves (L4-S3), which control the bladder detrusor and perineal floor.

The procedure for PTNS consists of the insertion of a needle above the medial malleolus near the posterior tibial nerve followed by the application of low voltage (10mA, 1–10 Hz frequency) electrical stimulation that produces sensory and motor responses (i.e., a tickling sensation and flexion of the big toe and/or fanning of all the toes). Noninvasive PTNS has also been delivered with surface electrodes. PTNS studies have reported 30-minute sessions given weekly for 4–12 weeks. The usual schedule is one 30-minute session once per week for twelve weeks. Consideration has been given to increasing the frequency of treatments to 3 times per week to speed achievement of desired outcomes.

PTNS is not cleared by the FDA for treating fecal incontinence; however, the treatment has been proposed for this purpose. The manufacturer recommends a course of treatment for fecal incontinence similar to the one used to treat overactive bladder (OAB); an initial course of 12 weekly sessions of tibial nerve
stimulation followed by a personalized schedule of follow-up treatments.

**REGULATORY STATUS:**

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**

   **Urinary Voiding Dysfunction**
   Originally, in 1997, the InterStim® System for Urinary Control (Medtronic, Inc., Minneapolis, MN) received premarket approval from the FDA “for the treatment of urinary urge incontinence, urinary retention, and significant symptoms of urgency/frequency in patients who have failed or could not tolerate more conservative treatments.

   In August 2001, the FDA approved the Model 3550-03 Twist-Lock Screening Cable and Model 3550-05 Percutaneous Extension and Tunneling Tool Kit for temporary SNS as part of a staged implant screening technique for patients who had inconclusive results following standard percutaneous testing (FDA, 2002). In 2007 the Urgent® PC Neuromodulation System (Uroplasty, Inc., Minnetonka, MN) received 510K approval as a substantially equivalent device. The Urgent PC Neuromodulation System is intended to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence.

   Nuro Neuromodulation System (Advanced Uro-Solutions Inc.). The Nuro Neuromodulation System (K132561) is a combination of a stimulator with permanently attached single insulated lead wire, and a number of single-use accessories that are sold separately, including: the acupuncture needle, needle holder, and electrode pad. The device was cleared on November 5, 2013 as minimally invasive neuromodulation systems designed to deliver retrograde access to the sacral nerve through percutaneous electrical stimulation of the tibial nerve. It is indicated for the treatment of patients with overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge urinary incontinence (UUI).

   **Fecal Incontinence**
   In March 2011, Medtronic, Inc. (Minneapolis, MN) received premarket approval from the FDA for the Medtronic® InterStim® Therapy System. This device is indicated for the treatment of chronic fecal incontinence in patients who have failed or cannot tolerate more conservative treatments (FDA, 2011). Medtronic is required to continue follow-up of the patients enrolled in the premarket InterStim trial for five years. The primary objective of the study, titled, “InterStim Sacral Nerve Stimulation Therapy for Bowel Control: Fecal Incontinence Post Approval Study (FI-PAS)” is to continue evaluation of incontinent episodes through five years post implantation of the device, including tracking of adverse events.

1. **CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):**

   **Sacral Nerve Stimulation for chronic fecal incontinence.** No CMS National Coverage Determination (NCD) was identified for sacral nerve stimulation for the treatment of chronic fecal incontinence.

   **Sacral Nerve Stimulation for Urinary Incontinence (NCD 230.18).**

   **Overview:**
   Effective January 1, 2002, sacral nerve stimulation is covered for the treatment of urinary urge
incontinence, urgency-frequency syndrome, and urinary retention. Sacral nerve stimulation involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. Both the test and the permanent implantation are covered.

Reimbursement Guidelines:
The following limitations for coverage apply to all three indications:

- Patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.
- Patients with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) which are associated with secondary manifestations of the above three indications are excluded.
- Patient must have had successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through voiding diaries.
- Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.

2. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):

Incontinence Treatment Systems

Covered Services: Incontinence treatment systems (Code: E0740), pelvic floor stimulator, monitor, sensor and/or trainer. Pelvic floor stimulators are covered with authorization for recipients with stress, urge or mixed incontinence who have undergone a documented trial of pelvic muscle exercises for a period of at least six months with no significant improvement in incontinence.

Non Covered Services:

- Pelvic floor stimulators are considered investigative for recipients who do not have stress, urge or mixed incontinence.
- Pelvic floor magnetic stimulation devices (e.g. ExMI, NeoControl Pelvic Floor System) are considered investigative.

Authorization is always required for pelvic floor stimulators. Documentation must include the type of incontinence and a trial of pelvic muscle exercises for a period of at least six months with no significant improvement in incontinence.

CLINICAL EVIDENCE:

SUMMARY:
Several systematic reviews, randomized clinical trials and prospective studies have demonstrated a decrease in the number of daily catheterizations required, an increase in the volume of urine obtained per void, and a decrease in postvoid residual urine volume in individuals with urinary voiding dysfunction (i.e., urinary urge incontinence, non-obstructive urinary retention, and urinary urgency/frequency syndrome) treated with sacral nerve stimulation (SNS) after demonstrating at least a 50% improvement in incontinence symptoms in response to a percutaneous screening trial of SNS.
The growing body of evidence evaluating SNS for fecal incontinence suggests that treatment with SNS results in decreased episodes of incontinence and improved quality of life in individuals in whom sphincter surgery is either not indicated or is contraindicated, there is an absence of a significant anorectal malformation or chronic inflammatory bowel disease involving the anus, and fecal incontinence is not secondary to another neurological condition and who have achieved at least 50% improvement in incontinence symptoms in response to a percutaneous screening trial of SNS.

Clinical utility has not been established, and SNS is not yet considered a standard treatment option for any other condition.

**APPLICABLE CODES:**

*The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.*

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<tr>
<td>A4290</td>
<td>Sacral nerve stimulation test lead, each</td>
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<td>E0745</td>
<td>Neuromuscular stimulator, electronic shock unit</td>
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<td>E1399</td>
<td>Durable medical equipment, miscellaneous (would include bulk leads, needles, and cables)</td>
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<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
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<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
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<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension</td>
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<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
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<td>04.92</td>
<td>Implantation or replacement of peripheral neurostimulator</td>
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<td>86.94</td>
<td>Insertion or replacement of single array neurostimulator pulse generator, not specified as rechargeable</td>
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<td>787.60-787.64</td>
<td>Incontinence of feces code range</td>
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<td>788.20-788.29</td>
<td>Retention of urine code range</td>
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<td>Urge incontinence code range</td>
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<td>R33.0-R33.9</td>
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<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
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<td>64566</td>
<td>Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming</td>
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<td>64581</td>
<td>Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
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<td>64585</td>
<td>Revision or removal of peripheral neurostimulator electrode array</td>
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<td>64590</td>
<td>Insertion or replacement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling</td>
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<td>64595</td>
<td>Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver</td>
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<td>95970</td>
<td>Electrical analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance, and patient compliance measurements); simple or complex brain, spinal cord or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming</td>
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<td>Single spinal cord or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter; with intraoperative or subsequent programming</td>
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REFERENCES:


183(4):1438-43.
112. Van Rey FS, Heesakkers JP. Applications of neurostimulation for urinary storage and voiding dysfunction in


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<td>Policy revised and approved by the Medical Policy Committee. Policy Number updated to 2016M0065B.</td>
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