

MEDICAL POLICY



SUBJECT: SACRAL NERVE STIMULATION	EFFECTIVE DATE: 11/19/99 REVISED DATE: 05/18/00, 08/16/01, 06/20/02, 6/19/03, 05/19/04, 05/18/05, 03/16/06, 2/15/07, 01/17/08, 01/15/09, 12/17/09, 02/17/11, 01/19/12, 01/17/13, 01/16/14, 01/22/15, 01/21/16, 01/19/17, 01/18/18
POLICY NUMBER: 7.01.10 CATEGORY: Technology Assessment	PAGE: 1 OF: 9

- *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*
- *If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.*
- *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT:

- I. Based upon our criteria and assessment of the peer-reviewed literature, sacral nerve stimulation has been medically proven to be effective and therefore, **medically appropriate** in patients with urge incontinence, urgency-frequency, and non-obstructive urinary retention that has not responded to conventional treatment (e.g., bladder retraining, dietary changes, pharmacologic interventions that includes at least two anticholinergics).
- II. Based upon our criteria and assessment of the peer-reviewed literature, sacral nerve stimulation has been medically proven to be effective and therefore, **medically appropriate** in patients with fecal incontinence when ALL the following indications have been met:
 - A. Chronic fecal incontinence of greater than 2 episodes per week with a duration greater than 6 months (or 12 months if occurring after vaginal childbirth); AND
 - B. Documented failure of conservative therapies (e.g., pharmacologic treatments, dietary changes) performed for more than 12 months; AND
 - C. Incontinence is not related to an anorectal malformation, chronic inflammatory bowel disease, or a neurologic condition such as peripheral neuropathy or complete spinal cord injury.
- III. Based upon our criteria and assessment of the peer-reviewed literature, sacral nerve stimulation has not been proven medically effective and is considered **investigational** for all other indications, including but not limited to, for the following conditions:
 - A. stress incontinence,
 - B. urge incontinence due to a neurological condition (e.g., diabetic neuropathy, multiple sclerosis, spinal cord injury);
 - C. other types of chronic voiding dysfunction;
 - D. constipation; or
 - E. chronic pelvic pain.

Refer to Corporate Medical Policy #1.01.19 regarding Pelvic Floor Stimulation as a Treatment for Urinary Incontinence.

Refer to Corporate Medical Policy # 7.01.66 regarding Radiofrequency Treatment for Fecal Incontinence.

Refer to Corporate Medical Policy #8.01.22 regarding Posterior Tibial Nerve Stimulation.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

- I. Prior to permanent implantation, patients must demonstrate an appropriate response to test stimulation. An appropriate response is defined as at least a 50% improvement in voiding/incontinence symptoms, or a 50% decrease in residual urine volume.
- II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

Proprietary Information of Excellus Health Plan, Inc.

<p>SUBJECT: SACRAL NERVE STIMULATION</p> <p>POLICY NUMBER: 7.01.10 CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99 REVISED DATE: 05/18/00, 08/16/01, 06/20/02, 6/19/03, 05/19/04, 05/18/05, 03/16/06, 2/15/07, 01/17/08, 01/15/09, 12/17/09, 02/17/11, 01/19/12, 01/17/13, 01/16/14, 01/22/15, 01/21/16, 01/19/17, 01/18/18</p> <p>PAGE: 2 OF 9</p>
--	--

DESCRIPTION:

Urinary voiding dysfunction is usually defined as the inability to control urination. Urinary voiding disorders are generally divided into five types, depending on the pathophysiology involved: urge incontinence-a subtype is urgency-frequency syndrome, overflow incontinence, also known as urinary retention, stress incontinence, mixed incontinence, and functional incontinence. Urge incontinence is defined as leakage of urine when there is a strong urge to void. Urgency-frequency is an uncontrollable urge to urinate, resulting in very frequent, small volumes. Urgency-frequency is a prominent symptom of interstitial cystitis. The term “overactive” bladder is frequently used when describing the symptoms of urgency-frequency and urge incontinence. Urinary retention is the inability to completely empty the bladder of urine.

Sacral nerve stimulation (SNS), or sacral nerve neuromodulation, is defined as the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. The SNS device consists of an implantable pulse generator that delivers controlled electrical impulses. This pulse generator is attached to wire leads 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.

Treatment using sacral nerve stimulation is one of several alternative modalities for patients with urinary urge incontinence, significant symptoms of urgency-frequency, or non-obstructive urinary retention who have failed behavioral (e.g., prompted voiding) and/or pharmacologic therapies.

Before implantation of the permanent device, patients undergo an initial testing phase to estimate potential response to treatment. The first type of testing developed was percutaneous nerve evaluation (PNE). This procedure is done with the patient under local anesthesia, using a test needle to identify the appropriate sacral nerve(s). Once identified, a temporary wire lead is inserted through the test needle and left in place for 4 to 7 days. This lead is connected to an external stimulator, which is carried by patients in their pocket or on their belt. If patients show a 50% or greater reduction in symptom frequency, they are deemed eligible for the permanent device. The second type of testing is a 2-stage surgical procedure. In the first stage, a quadripolar-tined lead is implanted (stage 1). The testing phase can last as long as several weeks, and if patients show a 50% or greater reduction in symptom frequency, they can proceed to stage 2 of the surgery, which is permanent implantation of the neuromodulation device. The 2-stage surgical procedure has been used in various ways. These include its use instead of PNE, for patients who failed PNE, for patients with an inconclusive PNE, or for patients who had a successful PNE to further refine patient selection. Approximately 63% of patients have a successful testing phase. The permanent device is implanted under general anesthesia, with the pulse generator inserted in the lower abdomen.

Sacral nerve stimulation is also under investigation and has been proposed as a treatment for chronic constipation and pelvic pain.

Sacral Nerve Stimulation for urinary incontinence needs to be distinguished from anterior sacral nerve root stimulation, which is indicated for a neurogenic bladder (VOCARE Bladder System).

RATIONALE:

The Interstim® Sacral Nerve Stimulation System (Medtronic) received pre-market approval for use in urge incontinence in 1997 and for urgency/frequency and nonobstructive urinary retention in 1999. In March 2011, Medtronic Inc. received premarket approval from the FDA for the use of InterStim® Therapy System for the treatment of fecal incontinence in patients who have failed or cannot tolerate more conservative treatments.

There is sufficient scientific evidence to conclude that sacral nerve stimulation is safe and effective for the treatment of urgency/frequency and non-obstructive urinary retention that is not of neurogenic origin and that health outcomes are improved. Good outcomes have been achieved outside investigational settings. Overall clinical success rates, defined by at least a 50% reduction in voiding dysfunction symptoms were 72%, 83% and 88% for patients with urge incontinence,

SUBJECT: SACRAL NERVE STIMULATION POLICY NUMBER: 7.01.10 CATEGORY: Technology Assessment	EFFECTIVE DATE: 11/19/99 REVISED DATE: 05/18/00, 08/16/01, 06/20/02, 6/19/03, 05/19/04, 05/18/05, 03/16/06, 2/15/07, 01/17/08, 01/15/09, 12/17/09, 02/17/11, 01/19/12, 01/17/13, 01/16/14, 01/22/15, 01/21/16, 01/19/17, 01/18/18 PAGE: 3 OF: 9
---	--

non-obstructive urinary retention and urinary urgency-frequency, respectively. The benefits of SNS have been reported to be sustained for up to 5 years in patients for whom there is long-term follow-up data available.

There is consistent and longer-term results from 2 large trials in 2010 (a prospective multicenter investigational trial with 120 patients and a European cohort of 177 patients) in support of sacral nerve stimulation for the treatment of fecal incontinence. Together with a randomized controlled trial with 12-month follow-up from 2008, evidence is considered sufficient for sacral nerve stimulation to be an option for the treatment for chronic fecal incontinence in well-selected patients who have failed conservative therapy. It should be emphasized that not all patients will benefit, and that the adverse event rate for this procedure, including serious adverse events, is high. Patients should therefore be provided with adequate information to make an informed choice regarding the potential risks and benefits of this procedure.

There is insufficient published data to draw conclusions about the efficacy of sacral nerve stimulation for patients with urinary frequency/urgency or retention of neurologic origin. Studies focusing on the use of sacral nerve stimulation for constipation and pelvic pain consist mostly of small case series with follow-up of short duration. The safety and efficacy of sacral nerve stimulation for these newer indications have yet to be proven in well-designed clinical trials. Currently, these are not approved FDA indications.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

<u>CPT:</u>	64561	Percutaneous implantation of neurostimulator electrode array, sacral nerve (transforaminal placement)
	64581	Incision for implantation of neurostimulator electrode array, sacral nerve (transforaminal placement)
	64585	Revision or removal of peripheral neurostimulator electrode array
	64590	Incision and subcutaneous placement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
	64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
	95970	Electronic analysis of implanted neurostimulator pulse generator system; simple or complex brain, spinal cord, or peripheral (e.g. cranial nerve, peripheral nerve, autonomic nerve, neuromuscular), neurostimulator pulse generator/transmitter, without reprogramming
	95971	simple spinal cord, or peripheral neurostimulator pulse generator/transmitter with intraoperative or subsequent programming
	95972	complex spinal cord, or peripheral neurostimulator pulse generator/ transmitter, with intraoperative or subsequent programming, first hour
	95973	complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour

Copyright © 2018 American Medical Association, Chicago, IL

<u>HCPCS:</u>	A4290	Sacral nerve stimulation test lead, each
----------------------	-------	--

SUBJECT: SACRAL NERVE STIMULATION POLICY NUMBER: 7.01.10 CATEGORY: Technology Assessment	EFFECTIVE DATE: 11/19/99 REVISED DATE: 05/18/00, 08/16/01, 06/20/02, 6/19/03, 05/19/04, 05/18/05, 03/16/06, 2/15/07, 01/17/08, 01/15/09, 12/17/09, 02/17/11, 01/19/12, 01/17/13, 01/16/14, 01/22/15, 01/21/16, 01/19/17, 01/18/18 PAGE: 4 OF: 9
---	--

- C1767 Generator, neurostimulator (implantable), nonrechargeable
- C1787 Patient programmer; neurostimulator
- C1820 Generator, neurostimulator (implantable), non high frequency with rechargeable battery and charging system
- C1822 Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system
- E0745 Neuromuscular stimulator, electronic shock unit
- L8680 Implantable neurostimulator electrode, each
- L8681 Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
- L8682 Implantable neurostimulator radiofrequency receiver
- L8683 Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
- L8684 Radiofrequency transmitter (external) for use with implantable sacral root stimulator receiver for bowel and bladder management, replacement
- L8685 Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
- L8686 Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
- L8687 Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
- L8688 Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
- L8689 External recharging system for battery (internal) for use with implantable neurostimulator

Investigational codes:

- ICD10:** K59.00-K59.09 Constipation (code range)
R10.2 Pelvic and perineal pain
N39.3 Stress incontinence (male or female)
N39.42 Incontinence without sensory awareness

Medically Appropriate Codes:

- ICD10:** N39.41 Urge incontinence
R15.0-R15.9 Fecal incontinence (code range)
R33.0-R33.9 Retention of urine (code range)
R35.0 Frequency of micturition

<p>SUBJECT: SACRAL NERVE STIMULATION</p> <p>POLICY NUMBER: 7.01.10</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 05/18/00, 08/16/01, 06/20/02, 6/19/03, 05/19/04, 05/18/05, 03/16/06, 2/15/07, 01/17/08, 01/15/09, 12/17/09, 02/17/11, 01/19/12, 01/17/13, 01/16/14, 01/22/15, 01/21/16, 01/19/17, 01/18/18</p> <p>PAGE: 5 OF: 9</p>
--	---

REFERENCES:

Altomare, et al. Long-term outcomes of sacral nerve stimulation for faecal incontinence. Br J Surg 2015 Mar;102(4):407-15.

American Urological Association (AUA). Guideline on diagnosis and treatment of overactive bladder. 2014 [https://www.auanet.org/education/guidelines/overactive-bladder.cfm] accessed 12/7/17.

*Amundsen CL, et al. Sacral neuromodulation in an older, urge-incontinent population. Am J Obstet Gynecol 2002 Dec;187(6):1462-5.

Amundsen CL, et al. Onabotulinumtoxin A vs sacral nerve neuromodulation on refractory urgency urinary incontinence in women. A randomized clinical trial. JAMA 2016;316(13):1366-1374.

BlueCross BlueShield Association. Medical Policy Reference Manual Policy #7.01.69. Sacral nerve neuromodulation/stimulation. 2017 Jan 12.

*BlueCross BlueShield Association Technology Evaluation Center (TEC). Sacral nerve stimulation for urinary incontinence. 2000 Aug;15(7).

*Bosch JLHR, et al. Sacral nerve neuromodulation in the treatment of patients with refractory motor urge incontinence: long-term results of a prospective longitudinal study. J Urol 2000 Apr;163(4):1219-22.

*Boyle DJ, et al. Efficacy of sacral nerve stimulation for fecal incontinence in patients with anal sphincter defects. Dis Colon Rectum 2009 Jul;52(7):1234-9.

*Boyle DJ, et al. Efficacy of sacral nerve stimulation for the treatment of fecal incontinence. Dis Colon Rectum 2011 Oct;54(10):1271-8.

Brueseke T, et al. Risk factors for surgical site infection in patients undergoing sacral nerve modulation therapy. Female Pelvic Med Reconstr Surg 2015 Jul-Aug;21(4):198-204.

*Caraballo R, et al. Sacral nerve stimulation as a treatment for urge incontinence and associated pelvic floor disorders at a pelvic floor center: a follow-up study. Urol 2001 Jun;57(Suppl 1):121.

*Caremel R, et al. Can sacral nerve neuromodulation improve incontinence symptoms in doubly incontinent patients successfully treated for major incontinence symptoms? Urology 2012 Jan;79(1):80-5.

*Carrierro A, et al. Sacral nerve stimulation for constipation: do we still miss something? Role of psychological evaluation. Int J Colorectal Dis 2010 Aug;25(8):1005-10.

*Chartier-Kastler EJ, et al. Long-term results of sacral nerve stimulation (S3) for the treatment of neurogenic refractory urge incontinence related to detrusor hyperreflexia. J Urol 2000 Nov;164(5):1476-80.

Chen G, et al. Sacral neuromodulation for neurogenic bladder and bowel dysfunction with multiple symptoms secondary to spinal cord disease. Spinal Cord 2014 Sep 16 [Epub ahead of print].

Chughtai B, et al. Long term safety of sacral nerve modulation in Medicare beneficiaries. Neurourol Urodyn 2014 Jul 25 [Epub ahead of print].

*Comiter CV. Sacral neuromodulation for the symptomatic treatment of refractory interstitial cystitis: a prospective study. J Urol 2003 Apr;169(4):1369-73.

Damon H, et al. Sacral nerve stimulation for fecal incontinence improves symptoms, quality of life and patients' satisfaction: results from a monocentric series of 119 patients. Int J Colorectal Dis 2013 Feb;28(2):227-33.

Dinning, et al. Treatment efficacy of sacral nerve stimulation in slow transit constipation: 1 two-phase, double-blind randomized controlled crossover study. Am J Gastroenterol 2015 May;110(5):733-40.

SUBJECT: SACRAL NERVE STIMULATION POLICY NUMBER: 7.01.10 CATEGORY: Technology Assessment	EFFECTIVE DATE: 11/19/99 REVISED DATE: 05/18/00, 08/16/01, 06/20/02, 6/19/03, 05/19/04, 05/18/05, 03/16/06, 2/15/07, 01/17/08, 01/15/09, 12/17/09, 02/17/11, 01/19/12, 01/17/13, 01/16/14, 01/22/15, 01/21/16, 01/19/17, 01/18/18 PAGE: 6 OF: 9
---	--

*Dudding TC, et al. Sacral nerve stimulation for the treatment of faecal incontinence related to dysfunction of the internal anal sphincter. Int J Colorectal Dis 2010 May;25(5):625-30.

Duelund-Jakobsen J, et al. Sacral nerve stimulation or faecal incontinence- efficacy confirmed from a two-centre prospectively maintained database. Int J Colorectal Dis 2016 Feb;31(2):421-428.

*El Gazzaz G, et al. Sacral neuromodulation for the treatment of fecal incontinence and urinary incontinence in female patients: long-term follow-up. Int J Colorectal Dis 2009 Dec;24(12):1377-81.

*Falletto E, et al. Is sacral nerve stimulation an effective treatment for chronic idiopathic anal pain? Dis Colon Rectum 2009 Mar;52(3):456-62.

*Faucheron JL, et al. Neuromodulation for fecal and urinary incontinence: functional results in 57 consecutive patients from a single institution. Dis Colon Rectum 2012 Dec;55(12):1278-83.

*Gajewski JB, et al. The long-term efficacy of sacral neuromodulation in the management of intractable cases of bladder pain syndrome: 14 years experience in one centre. BJU Int 2011 Apr;107(8):1258-64.

*George AT, et al. Long-term outcomes of sacral nerve stimulation for fecal incontinence. Dis Colon Rectum 2012 Mar;55(3):302-6.

*Gormley EA, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline. J Urol 2012 Dec;188(6 Suppl):2455-63.

*Govaert B, et al. Medium-term outcome of sacral nerve modulation for constipation. Dis Colon Rectum 2012 Jan;55(1):26-31.

*Groen J, et al. Sacral neuromodulation as treatment for refractory idiopathic urge urinary incontinence: 5-year results of a longitudinal study in 60 women. J Urol 2011 Sep;186(3):954-9.

*Hassouna MM, et al. Sacral neuromodulation in the treatment of urgency-frequency symptoms: a multicenter study on efficacy and safety. J Urol 2000 Jun;163:1849-54.

*Hehenfellner M, et al. Chronic sacral neuromodulation for treatment of neurogenic bladder dysfunction: long-term results with unilateral implants. Urol 2001 Dec;58(6):887-92.

*Herbison GP, et al. Sacral neuromodulation with implanted devices for urinary storage and voiding dysfunction in adults. Cochrane Database Syst Rev. 2009 Apr 15;(2):CD004202.

Hotouras A, et al. Outcome of sacral nerve stimulation for fecal incontinence in patients refractory to percutaneous tibial nerve stimulation. Dis Colon Rectum 2013 Jul;56(7):915-20.

Hull T, et al. Long-term durability of sacral nerve stimulation therapy for chronic fecal incontinence. Dis Colon Rectum 2013 Feb;56(2):234-45.

Irwin GW, et al. Outcomes of sacral nerve stimulation for faecal incontinence in Northern Ireland. Ulster Med J 2017 Jan;86(1):20-24.

Johnson BL 3rd, et al. Is sacral neuromodulation here to stay? Clinical outcomes of a new treatment for fecal incontinence. J Gastrointest Surg 2014 Aug 13 [Epub ahead of print].

*Kamm MA, et al. Sacral nerve stimulation for intractable constipation. Gut 2010 Mar;59(3):333-40.

*Kenefick NJ, et al. Double-blind placebo-controlled crossover study of sacral nerve stimulation for idiopathic constipation. Br J Surg 2002 Dec; 89(12):1570-1.

*Kenefick NJ, et al. Sacral nerve stimulation for faecal incontinence due to systemic sclerosis. Gut 2002 Dec;51(6):881-3.

SUBJECT: SACRAL NERVE STIMULATION POLICY NUMBER: 7.01.10 CATEGORY: Technology Assessment	EFFECTIVE DATE: 11/19/99 REVISED DATE: 05/18/00, 08/16/01, 06/20/02, 6/19/03, 05/19/04, 05/18/05, 03/16/06, 2/15/07, 01/17/08, 01/15/09, 12/17/09, 02/17/11, 01/19/12, 01/17/13, 01/16/14, 01/22/15, 01/21/16, 01/19/17, 01/18/18 PAGE: 7 OF: 9
---	--

- *Kenefick NJ, et al. Permanent sacral nerve stimulation for treatment of idiopathic constipation. Br J Surg 2002 Jul;89(7):882-8.
- *Knowles CH, et al. Prospective randomized double-blind study of temporary sacral nerve stimulation in patients with rectal evacuatory dysfunction and rectal hyposensitivity. Ann Surg 2012 Apr;255(4):643-9.
- *Koch SM, et al. Sacral nerve modulation and other treatments in patients with faecal incontinence after unsuccessful pelvic floor rehabilitation: a prospective study. Colorectal Dis 2010 Apr;12(4):334-41.
- *Kohli N, et al. Neuromodulation techniques for the treatment of the overactive bladder. Clin Obstet Gynecol 2002 Mar;45(1):218-32.
- *Leroi AM, et al. Sacral nerve stimulation in faecal incontinence: position statement based on a collective experience. Colorectal Dis 2009 Jul;11(6):572-83.
- *Lim JT, et al. Sacral nerve stimulation for fecal incontinence: long-term outcomes. Dis Colon Rectum 2011 Aug;54(8):969-74.
- *Maeda Y, et al. Sacral nerve stimulation for constipation: suboptimal outcome and adverse events. Dis Colon Rectum 2010 Jul;53(7):995-9.
- *Maeda Y, et al. Postoperative issues of sacral stimulation for fecal incontinence and constipation: a systematic literature review and treatment guideline. Dis Colon Rectum 2011 Nov;54(11):1443-60.
- *Maher CF, et al. Percutaneous sacral nerve root neuromodulation for intractable interstitial cystitis. J Urol 2001 Mar;165:884-6.
- *Marcellissen TA, et al. Psychological and psychiatric factors as predictors for success in sacral nerve neuromodulation treatment. BJU Int 2011 Dec;108(11):1834-8.
- *Matzel KE, et al. Sacral nerve stimulation for faecal incontinence: multicentre study. Lancet 2004 Apr;17;363(9417):1270-6.
- *Matzel KE, et al. Sacral nerve stimulation in faecal incontinence: long-term outcome. Colorectal Dis 2009 Jul;11(6):636-41.
- *Melenhorst J, et al. Sacral nerve neuromodulation in patients with faecal incontinence: results of the first 100 permanent implantations. Colorectal Dis 2007 Oct;9(8):725-30.
- *Mellgren A, et al. Long-term efficacy and safety of sacral nerve stimulation for fecal incontinence. Dis Colon Rectum 2011 Sep;54(9):1065-75.
- *Michelsen HB, et al. Rectal volume tolerability and anal pressures in patients with fecal incontinence treated with sacral nerve stimulation. Dis Colon Rectum 2006 Jul;49(7):1039-44.
- *Michelsen HB, et al. Six years experience with sacral nerve stimulation for fecal incontinence. Dis Colon Rectum 2010 Apr;53(4):414-21.
- *Mowatt G, et al. Sacral nerve stimulation for faecal incontinence and constipation in adults. Cochrane Database Syst Rev 2007 Jul 18;(3):CD004464.
- National Institute for Health and Care Excellus (NICE). Sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention. IPG536. Nov 2015. [<https://www.nice.org.uk/guidance/ipeg536>]. Accessed 11/30/17.
- Noblett, et al. Results of a prospective, multicenter study evaluating quality of life, safety, and efficacy of sacral neuromodulation at twelve months in subjects with symptoms of overactive bladder. Neurourol Urodyn 2014 Dec 24 [Epub ahead of print].

<p>SUBJECT: SACRAL NERVE STIMULATION</p> <p>POLICY NUMBER: 7.01.10</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 05/18/00, 08/16/01, 06/20/02, 6/19/03, 05/19/04, 05/18/05, 03/16/06, 2/15/07, 01/17/08, 01/15/09, 12/17/09, 02/17/11, 01/19/12, 01/17/13, 01/16/14, 01/22/15, 01/21/16, 01/19/17, 01/18/18</p> <p>PAGE: 8 OF: 9</p>
--	---

*Ortiz H, et al. Functional outcome of sacral nerve stimulation in patients with severe constipation. Dis Colon Rectum 2012 Aug;55(8):876-80.

*Robert-Yap J, et al. Sacral nerve modulation in the treatment of fecal incontinence following repair of rectal prolapse. Dis Colon Rectum 2010 Apr;53(4):428-31.

*Ripetti V, et al. Sacral nerve neuromodulation improves physical, psychological and social quality of life in patients with fecal incontinence. Tech Coloproctol 2002 Dec;6(3):147-52.

*Santoro GA, et al. Sacral nerve stimulation for fecal incontinence related to external sphincter atrophy. Dis Colon Rectum 2012 Jul;55(7):797-805.

*Siddiqui NY, et al. Efficacy and adverse events of sacral nerve stimulation for overactive bladder: A systematic review. Neurourol Urodyn 2010;29 Suppl 1:S18-23.

*Siegel S, et al. Sacral nerve stimulation in patients with chronic intractable pelvic pain. J Urol 2001 Nov;166(5):1742-5.

Siegel S, et al. Results of a prospective, randomized, multicenter study evaluating sacral neuromodulation with Interstim therapy compared to standard medical therapy at 6-months in subjects with mild symptoms of overactive bladder. Neurourol Urodyn 2015 Mar 34;(3):224-30.

Smits MA, et al. Sacral neuromodulation in patients with idiopathic overactive bladder after initial botulinum toxin therapy. J Urol 2013 Dec;190(6):2148-52.

Stephany HA, et al. Prospective evaluation of sacral nerve modulation in children with validated questionnaires. J Urol 2013 Oct;190(4 Suppl):1516-22.

*Sutherland SE. et al. Sacral nerve stimulation for voiding dysfunctions: One institution's 11-year experience. Neurourol Urodyn 2007;26(1):19-28.

*Tan E, et al. Meta-analysis: sacral nerve stimulation versus conservative therapy in the treatment of faecal incontinence. Int J Colorectal Dis 2011 Mar;26(3):275-94.

Thaha MA, et al. sacral nerve stimulation for faecal incontinence and constipation in adults. Cochrane Database Syst Rev 2015 Aug 24;8:CD004464.

Thin NN, et al. Systematic review of the clinical effectiveness of neuromodulation in the treatment of faecal incontinence. Br J Surg 2013 Oct;100(11):1430-47.

Thin NN, et al. Randomized trial of sacral versus percutaneous tibial stimulation in patients with faecal incontinence. Br J Surg 2015 Mar;102(4):349.

Thomas GP, et al. Sacral nerve stimulation for constipation. Br J Surg 2013 Jan;100(2):174-81.

Thomas GP, et al. A review of sacral nerve stimulation for faecal incontinence following rectal surgery and radiotherapy. Colorectal Dis 2015 Nov;17(11):939-942.

Tirlapur SA, et al. Nerve stimulation for chronic pelvic pain and bladder pain syndrome: a systematic review. Acta Obstet Gynecol Scand 2013 Aug;92(8):881-7.

*Tjandra JJ, et al. Standards Practice task Force of the American Society of Colon and Rectal Surgeons. Practice parameters for the treatment of fecal incontinence. Dis Colon Rectum 2007 Oct;50(10):1497-507.

*Van Voskuilen AC, et al. Long term results of neuromodulation by sacral nerve stimulation for lower urinary tract symptoms: a retrospective single center study. Eur Urol 2006 Feb;49(2):366-72.

*Van Wunnik BP, et al. Sacral neuromodulation therapy: a promising treatment for adolescents with refractory functional constipation. Dis Colon Rectum 2012 Mar;55(3):278-85.

<p>SUBJECT: SACRAL NERVE STIMULATION</p> <p>POLICY NUMBER: 7.01.10 CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99 REVISED DATE: 05/18/00, 08/16/01, 06/20/02, 6/19/03, 05/19/04, 05/18/05, 03/16/06, 2/15/07, 01/17/08, 01/15/09, 12/17/09, 02/17/11, 01/19/12, 01/17/13, 01/16/14, 01/22/15, 01/21/16, 01/19/17, 01/18/18</p> <p>PAGE: 9 OF: 9</p>
--	---

*Wallace PA, et al. Sacral nerve neuromodulation in patients with underlying neurologic disease. Am J Obstet Gynecol 2007 Jul;197(1):96.e1-5.

*Wexner SD, et al. Sacral nerve stimulation for fecal incontinence: results of a 120-patient prospective multicenter study. Ann Surg 2010 Mar;251(3):441-9.

*White WM, et al. Sacral nerve stimulation for refractory overactive bladder in the elderly population. J Urol 2009 Oct;182(4):1449-52.

Williams AE, et al. SaFaRI: sacral nerve stimulation versus the FENIX magnetic sphincter augmentation for adult faecal incontinence: a randomized investigation. Int J Colorectal Dis 2016 Feb;31(2):465-472.

Zerbib F, et al. Randomized clinical trial of sacral nerve stimulation for refractory constipation. Br J Surg 2017 Feb;104(3):205-213.

*key article

KEY WORDS:

Fecal incontinence, Interstim®, Neuromodulation, Urge incontinence, Urgency-frequency, Urinary retention.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for sacral nerve stimulation for urinary incontinence. Please refer to the following NCD website for Medicare Members:

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=249&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York++Upstate&CptHcpcsCode=36514&bc=gAAAABAAAA&>