

Corporate Medical Policy

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

File Name: sacral_nerve_neuromodulation_stimulation_for_pelvic_floor_dysfunction
Origination: 5/2000
Last CAP Review: 11/2021
Next CAP Review: 11/2022
Last Review: 11/2021

Description of Procedure or Service

Sacral nerve stimulation (SNS), also referred to as sacral nerve neuromodulation (SNM), involves the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. This policy addresses use of SNS in the treatment of urinary or fecal incontinence, fecal non-obstructive retention, and chronic pelvic pain in patients with intact neural innervation of the bladder and/or rectum.

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 (also called bladder pain syndrome.) Urinary retention is the inability to completely empty the bladder of urine. Fecal incontinence can arise from a variety of mechanisms, including rectal wall compliance, efferent and afferent neural pathways, central and peripheral nervous systems, and voluntary and involuntary muscles. Fecal incontinence is more common in women, due mainly to muscular and neural damage that may occur during vaginal delivery.

Sacral nerve stimulation treatment is one of several alternative modalities for patients with urinary or fecal incontinence (urge incontinence, significant symptoms of urgency-frequency, nonobstructive urinary retention) who have failed behavioral (eg, prompted voiding) and/or pharmacologic therapies.

The SNM 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.

Prior to 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 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. Patients then keep track of voiding symptoms while the temporary device is functioning. The results of this test phase are used to determine whether patients are appropriate candidates for the permanent device. 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

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

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.

The permanent device is implanted with the patient under general anesthesia. An incision is made over the lower back, and the electrical leads are placed in contact with the sacral nerve root(s). The wire leads are extended through a second incision underneath the skin across the flank to the lower abdomen. Finally, a third incision is made in the lower abdomen where the pulse generator is inserted and connected to the wire leads. Following implantation, the physician programs the pulse generator to the optimal settings for that patient. The patient can switch the pulse generator between on and off by placing the control magnet over the area of the pulse generator for 1–2 seconds.

In 1997, the Medtronic InterStim® Sacral Nerve Stimulation system received U.S. Food and Drug Administration (FDA) approval for marketing for the indication of urinary urge incontinence in patients who have failed or could not tolerate more conservative treatments. In 1999, the device received FDA approval for the additional indications of urgency-frequency and urinary retention in patients without mechanical obstruction.

In 2006, the Medtronic InterStim® II System received FDA approval for treatment of intractable cases of overactive bladder and urinary retention. The new device is smaller and lighter than the original system and is reported to be suited for those with lower energy requirements or small stature. The device also includes updated software and programming options.

In 2011, the Medtronic InterStim System® received FDA approval for the indication of chronic fecal incontinence in patients who have failed or could not tolerate more conservative treatments. The InterStim device has not been specifically approved by FDA for treatment of chronic pelvic pain.

Related Policies

Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence
Percutaneous Tibial Nerve Stimulation for Voiding Dysfunction

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Sacral Nerve Neuromodulation/Stimulation is covered

Urinary Incontinence and Non-obstructive Retention

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:

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

- a. Urge incontinence,
 - b. Urgency-frequency syndrome,
 - c. Non-obstructive urinary retention,
 - d. Overactive bladder.
2. There is documented failure or intolerance to at least two conventional therapies (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy)
 3. The patient is an appropriate surgical candidate
 4. 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 (1-4) above are met.
2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

Fecal Incontinence

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 two incontinent episodes on average per week with duration greater than 6 months or for more than 12 months after vaginal childbirth; AND
2. There is documented failure 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; AND
3. The patient is an appropriate surgical candidate; AND
4. The condition is not related to an 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; AND
5. Incontinence is not related to another neurologic condition; AND
6. The patient has not had rectal surgery in the previous 12 months, or in the case of cancer, the patient has not had rectal surgery in the past 24 months.

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 (1-6) above are met.

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

When Sacral Nerve Neuromodulation/Stimulation is not covered

Other urinary/voiding applications of sacral nerve neuromodulation are considered investigational, including but not limited to treatment of the following:

1. stress incontinence or urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia, multiple sclerosis, spinal cord injury, other types of chronic voiding dysfunction);
2. patients with mechanical urethral obstruction such as benign prostatic hypertrophy, cancer or urethral stricture;
3. conditions which have responded to behavioral and pharmacological interventions.

Sacral nerve neuromodulation is also considered investigational in the treatment of chronic constipation or chronic pelvic pain.

Policy Guidelines

For individuals with urinary incontinence who have failed conservative treatment who receive SNM, the evidence includes randomized controlled trials (RCTs) and case series. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. Results from the RCTs and case series with long-term follow-up have suggested that SNM reduces symptoms of urge incontinence, urgency-frequency syndrome, nonobstructive urinary retention, and overactive bladder in selected patients. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with fecal incontinence who have failed conservative treatment who receive SNM, the evidence includes RCTs, systematic reviews, and observational studies including several with long-term follow-up. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. Although relatively small, the available trials had a low risk of bias and demonstrated improvements in incontinence relative to alternatives in selected patients. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with constipation who have failed conservative treatment who receive SNM, the evidence includes RCTs, systematic reviews, and case series including several with long-term follow-up. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. The available trials have not consistently reported improvements in outcomes with SNM. Additional studies are needed to demonstrate the health benefits of this technology. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with chronic pelvic pain who receive SNM, the evidence is limited to case series. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbssc.com. They are listed in the Category Search on the Medical Policy search page.

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

Applicable codes: 64561, 64581, 64585, 64590, 64595, 95970, 95971, 95972, A4290, E0745, L8679, L8680, L8681, L8682, L8683, L8684, L8685, L8686, L8687, L8688, L8689

ICD-10 diagnosis codes: R15.0, R15.1, R15.2, R15.9, R32, R33.0, R33.8, R33.9, R39.14, N39.3, N39.41, N39.42, N39.43, N39.44, N39.45, N39.46, N39.490, N39.491, N39.492, N39.498

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

From Policy entitled: Sacral Nerve Stimulation for Urinary Incontinence

National Association TEC evaluation. Volume 13, Tab 18 - 10/1998

BCBSA Medical Policy Reference Manual - 12/1999

Independent Consultant Review - 3/2000

Medical Policy Advisory Group - 4/2000

Specialty Matched Consultant Advisory Panel. No changes to policy - 12/2000

From policy entitled: Treatment of Urinary Incontinence

BCBSA TEC Evaluation, June 2000; Volume 15, No. 2

BCBSA TEC Evaluation, August 2000; Volume 15, No. 8

BCBSA Medical Policy Reference Manual, 12/15/00; 1.01.17

Specialty Matched Consultant Advisory Panel - 5/2001

Specialty Matched Consultant Advisory Panel - 9/2001

BCBSA Medical Policy Reference Manual, 2/15/02; 7.01.69

BCBSA Medical Policy Reference Manual, 12/18/02; 7.01.69

BCBSA Medical Policy Reference Manual, 12/18/02; 1.01.17

BCBSA Medical Policy Reference Manual, 4/29/03; 7.01.19

Specialty Matched Consultant Advisory Panel - 5/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 7/15/04.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 4/15/04.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.60, 11/9/04

Specialty Matched Consultant Advisory Panel - 5/2005

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

From policy entitled: Sacral Nerve Modulation/Stimulation for Urinary Incontinence

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 6/27/05.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 12/14/05.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 7/20/06.

Medtronic website: InterStim Therapy: Indications, contraindications, warnings, precautions and adverse events. Accessed on 5/8/07 at <http://www.medtronic.com/physician/interstim/disclosure.html>

Specialty Matched Consultant Advisory Panel - 5/8/2007

Policy re-titled: Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

Blue Cross and Blue Shield Association. Technology Evaluation Criteria (TEC) Assessment, 1998; Tab 18.

Weil EH, Ruiz-Cerda JL, Eerdmans PH et al. Sacral root neuromodulation in the treatment of refractory urinary urge incontinence: a prospective randomized clinical trial. *Eur Urol* 2000; 37(2):161-71.

Blue Cross and Blue Shield Association. Technology Evaluation Criteria (TEC) Assessment, 2000; Tab 7.

Maher CF, Carey MP, Dwyer PL et al. Percutaneous sacral nerve root neuromodulation for intractable interstitial cystitis. *J Urol* 2001; 165(3):884-6.

Payne CK, Whitmore KE, Diokno AC et al. Sacral neuromodulation in patients with interstitial cystitis: a multicenter clinical trial. *Neurourol Urodyn* 2001; 20:554-5.

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

Brazzelli M, Murray A, Fraser C. Efficacy and safety of sacral nerve stimulation for urinary urge incontinence: a systematic review. *J Urol* 2006; 175(3 pt 1):835-41.

Medtronic. Summary of Multi-Center Clinical Study. Medtronic Neurological, Minneapolis, MN. See also Web site: www.interstim.com

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

Wallace PA, Lane FL, Noblett KL. Sacral nerve neuromodulation in patients with underlying neurologic disease. *Am J Obstet Gynecol* 2007; 197(1):96.

White WM, Mobley JD 3rd, Doggweiler R, et al. Incidence and Predictors of Complications With Sacral

Neuromodulation. *Urology* 2009 Feb 3. [Epub ahead of print]

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

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

Kenefick NJ, Vaizey CJ, Cohen RC et al. Medium term results of permanent sacral nerve stimulation for faecal incontinence. *Br J Surg* 2002; 89(7):896-901.

Rosen HR, Urbarz C, Holzer B et al. Sacral nerve stimulation as a treatment for fecal incontinence. *Gastroenterology* 2001; 121(3):536-41.

Ganio E, Ratto C, Masin A et al. Neuromodulation for fecal incontinence: outcome in 16 patients with definitive implant. *Dis Colon Rectum* 2001; 44(7):965-70.

Ganio E, Luc AR, Clerioco G et al. Sacral nerve stimulation for treatment of fecal incontinence. *Dis Colon Rectum* 2001; 44(5):619-31

Matzel KE, Kamm MA, Stosser M et al. Sacral spinal nerve stimulation for faecal incontinence: multicentre study. *Lancet* 2004; 363(9417):1270-6.

Leroi AM, Parc Y, Lehur PA et al. Efficacy of sacral nerve stimulation for fecal incontinence: results of a multicenter double-blind crossover study. *Ann Surg* 2005; 242(5):662-9.

Mowatt G, Glazener C, Jarrett M. Sacral nerve stimulation for fecal incontinence and constipation in adults: a short version Cochrane review. *Neurourol Urodyn* 2008;27(3):155-61.

Tjandra JJ, Chan MK, Yeh CH, et al. Sacral nerve stimulation is more effective than optimal medical therapy for severe fecal incontinence: a randomized, controlled study. *Dis Colon Rectum* 2008; 51(5):494-502.

Matzel KE, Lux P, Heuer S, Besendörfer M, Zhang W. Sacral nerve stimulation for faecal incontinence: Long-term outcome. *Colorectal Dis*. 2008 Aug 21. [Epub ahead of print]

Kenefick NJ, Nicholls RJ, Cohen RG et al. Permanent sacral nerve stimulation for treatment of idiopathic constipation. *Br J Surg* 2002; 89(7):882-8.

Malouf AJ, Wiesel PH, Nicholls T et al. Short-term effects of sacral nerve stimulation for idiopathic slow transit constipation. *World J Surg* 2002; 26(2):166-70.

Holzer B, Rosen HR, Novi G, et al. Sacral nerve stimulation in patients with severe constipation. *Dis Colon Rectum* 2008; 51(5):524-29.

Siegel S, Paszkiewicz E, Kirkpatrick C et al. Sacral nerve stimulation in patient with chronic intractable pelvic pain. *J Urol* 2001; 166(5):1742-5.

Rao SS; American College of Gastroenterology Practice Parameters Committee. Diagnosis and management of fecal incontinence. American College of Gastroenterology Practice Parameters Committee. *Am J Gastroenterol* 2004; 99(8):1585-604.

Centers for Medicare and Medicaid Services. National Coverage Determination for Sacral Nerve Stimulation for Urinary Incontinence. Manual Section Number 230.18. Retrieved on June 15, 2009 from http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=230.18&ncd_version=1&basket=ncd%3A230%2E18%3A1%3ASacral+Nerve+Stimulation+For+Urinary+Incontinence

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 9/18/07.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 5/14/09.

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

Specialty Matched Consultant Advisory Panel - 9/8/09

Wexner SD, Collier JA, Devroede G et al. Sacral nerve stimulation for fecal incontinence: results of a 120-patient prospective multicenter study. *Ann Surg* 2010; 251(3):441-9. Abstract retrieved on May 14, 2010 from <http://www.ncbi.nlm.nih.gov/pubmed/20160636>

Michelsen HB, Thompson-Fawcett M, Lundby L et al. Six years of experience with sacral nerve stimulation for fecal incontinence. *Dis Colon Rectum* 2010; 53(4):414-21. Abstract retrieved on May 14, 2010 from <http://www.ncbi.nlm.nih.gov/pubmed/20305440>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 5/13/10

Specialty Matched Consultant Advisory Panel review 12/2010

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 5/12/11

National Institute for Clinical Evidence (NICE). Faecal incontinence: the management of faecal incontinence in adults. NICE clinical guideline 49. Retrieved on November 3, 2011 from <http://www.nice.org.uk/CG49>.

Cameron AP, Anger JT, Madison R, Saigal CS, Clemens JQ. Urologic Diseases in America Project. National trends in the usage and success of sacral nerve test stimulation. *J Urol*. 2011 March; 185(3): 970–975. Retrieved on May 16, 2012 from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3285387/?tool=pubmed>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 4/12/12

Medical Director review 5/2012

Specialty Matched Consultant Advisory Panel review 11/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 4/11/13

Medical Director review 5/2013

Specialty Matched Consultant Advisory Panel review 11/2013

Medical Director review 12/2013

Siegel S, Noblett K, Mangel J et al. Results of a prospective, randomized, multicenter study evaluating sacral neuromodulation with InterStim therapy compared with standard medical therapy at 6-months in subjects with mild symptoms of overactive bladder. *Neurourol Urodyn* 2014.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 4/10/14

Leroi AM, Parc Y, Lehur PA et al. Efficacy of sacral nerve stimulation for fecal incontinence: results of a multicenter double-blind crossover study. *Ann Surg* 2005; 242(5):662-9. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1409867/>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 7/10/14

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

Specialty Matched Consultant Advisory Panel 11/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 7/9/15

Specialty Matched Consultant Advisory Panel 11/2015

Specialty Matched Consultant Advisory Panel 11/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 1/12/2017

Specialty Matched Consultant Advisory Panel 11/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 4/12/2018

Specialty Matched Consultant Advisory Panel 11/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 4/8/2019

Specialty Matched Consultant Advisory Panel 11/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 4/16/2020

Specialty Matched Consultant Advisory Panel 11/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 4/8/2021

Specialty Matched Consultant Advisory Panel 11/2021

Policy Implementation/Update Information

From policy entitled: Sacral Nerve Stimulation for Urinary Incontinence

4/00 Medical Policy Advisory Group.

5/00 Original policy issued.

12/00 Specialty Matched Consultant Advisory Panel. No changes to policy. System coding changes; added 2001 HCPCS codes A4290, E0756, E0757, E0758.

From policy entitled: Treatment of Urinary Incontinence

5/01 Policies combined and renamed. Added criteria for Pelvic Floor Stimulation as a Treatment of Urinary Incontinence. Specialty Matched Consultant Advisory Panel. No changes to policy.

9/01 Specialty Matched Consultant Advisory Panel review. Added description and coverage criteria for carbon-coated spheres or beads for Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence.

10/01 Coding format changes.

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

- 3/02 Added codes 64561 and 64581 to the Billing/Coding Section in Section II Sacral Nerve Stimulation for Urinary Incontinence and System Application Guidelines.
- 4/02 Format changes.
- 11/03 Specialty Matched Consultant Advisory Panel review 5/23/03. Benefits Application section revised. For Section I, Periurethral Injection of Implant Material, revised description for clarity; revised Policy Guidelines to indicate that "Patients whose incontinence does not improve with five injection procedures....". For Section II, Sacral Nerve Stimulation, removed codes 64555, 64575, E0751, E0753, E1399 and added codes 95971, E0752 and E0759. For Section III, Pelvic Floor Stimulation, revised description for clarity; added Innova Feminine Incontinence Treatment System to this section; added code 0029T to Billing/Coding section and removed codes 97014 and 97032. Deleted Section IV, Innova Feminine Incontinence Treatment System.
- 2/04 Added HCPCS codes L8603 and Q3031 to Billing/Coding section of Section I re: Periurethral Injection of Implant Material.
- 6/16/05 Specialty Matched Consultant Advisory Panel review 5/24/05. Section I - Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence; description revised, included biocompatible copolymer implant (e.g., URYX) in description; For "When Covered"- 2.d. "Cross-linked collagen or carbon-coated beads are used as the implantable material." pulled out as a separate sentence so need 1 or 2 and use of listed materials; also added biocompatible copolymers as one of the approved materials; For "When not Covered" added "The use of autologous fat and autologous ear chondrocytes as periurethral bulking agents are considered investigational and are not covered."; For "Policy Guidelines" removed sentence re: "15 ml of paste are injected..." since the procedure is included in the description. Section II - Sacral Nerve Modulation/Stimulation...description of procedure revised to provide additional information; For "When Covered" - changed #2 to indicate that the urinary incontinence conditions listed in #1 should not be related to a neurologic condition; #3 now reads: "Medical records document that the patient has failed at least a 3 month trial of conservative treatment such as behavioral therapy (i.e., diet modification, bladder training, biofeedback, Kegel exercises) and/or pharmacotherapy (i.e., 2 or more anti-cholinergic drugs or a combination of an anti-cholinergic and a tricyclic anti-depressant); #4 is now re: the percutaneous test stimulation. For "When not Covered" #1 - added several examples of conditions "Any conditions other than those listed above including but not limited to the following: stress incontinence, urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia, multiple sclerosis or spinal cord injury), other types of chronic voiding dysfunction, patients with mechanical urethral obstruction such as benign prostatic hypertrophy, cancer or urethral stricture." Section III - Pelvic Floor Stimulation...added policy guidelines re: investigational status: "Available data are insufficient to determine whether this treatment is as effective as alternatives. Additionally, the treatments lack standardization of delivery. There are minimal data for magnetic stimulation and no randomized trials. There is insufficient medical and scientific evidence to permit the Plan to evaluate the therapeutic value of pelvic floor stimulation as a treatment of urinary incontinence. For further information, please refer to separate policy number MED1263, Investigational (Experimental) Services." Added - Section IV re: Transvaginal Radiofrequency Bladder Neck Suspension for Urinary Stress Incontinence as investigational. Notice given 6/16/05. Effective date 8/18/05.
- 1/5/06 Removed deleted codes E0752, E0756, E0757, E0758 & E0759 from appropriate Billing/Coding sections.

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

2/26/07 Added HCPCS codes L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689 to Section II - Sacral Nerve Modulation/Stimulation for Urinary Incontinence. (pmo)

From policy entitled: Sacral Nerve Modulation/Stimulation for Urinary Incontinence

6/4/07 Section II (Sacral Nerve Modulation/Stimulation for Urinary Incontinence) of the policy entitled "Urinary Incontinence, Treatment " issued as a separate policy entitled "Sacral Nerve Modulation/Stimulation for Urinary Incontinence". Specialty Matched Consultant Advisory Panel review 5/8/07. No changes to criteria. Policy Guidelines and Reference sources added. (pmo)

Policy re-titled: Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

2/2/10 Description and Policy Guidelines sections updated. When Covered section revised. Previous statement under Policy Guidelines re: inadequate data regarding the Interstim® device in patients with chronic pelvic pain, constipation and fecal incontinence moved to When Not Covered section as investigational. HCPCS code L8684 added to Billing/Coding section. Reference sources added. (pmo)

7/20/10 Description section updated. Removed Medical Policy number. References updated. Updated Policy Guidelines. When Covered section updated to include fecal incontinence with the following criteria: “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; AND documented failure or intolerance to conventional therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy performed more than 12 months [or 24 months in case of cancer] previously); AND the patient is an appropriate surgical candidate; AND a successful percutaneous test stimulation, defined as at least 50% improvement in symptoms, was performed; AND condition is not related to an 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; AND incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.” (mco)

1/18/11 Specialty Matched Consultant Advisory Panel review 12/2010. References updated. (mco)

7/19/11 Updated “Description” section to include FDA approval of Medtronic InterStim® System to treat chronic fecal incontinence in patients who have failed conservative treatments. References updated. (mco)

12/20/11 Specialty Matched Consultant Advisory Panel review 11/2011. References updated. Policy Guidelines updated. (mco)

6/12/12 Description section updated. “When Covered” section revised. Medically necessary policy statement for urinary incontinence changed to 2-part statement as follows: **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. Urge incontinence, b. Urgency-frequency, c. Non-obstructive urinary retention. 2. There is documented failure or intolerance to at least two conventional therapies (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy) 3. Incontinence is not related to a neurologic condition.

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

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 (1-3) above are met. 2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 2 weeks. Policy Guidelines updated. References updated. Medical Director review 5/2012. (mco)

- 1/15/13 Specialty Matched Consultant Advisory Panel review 11/2012. No changes to Policy Statements. (mco)
- 6/11/13 “When Covered” section revised. The length of successful percutaneous test stimulation in medically necessary statements changed from at least 2 weeks to at least 1 week. Fecal incontinence information separated into 2 statements; 1 on trial stimulation and 1 on permanent implantation. Added the following criterion to the “When Covered” statements: “3. The patient is an appropriate surgical candidate.” References updated. Medical Director review 5/2013. (mco)
- 12/31/13 Specialty Matched Consultant Advisory Panel review 11/2013. Added the following codes to the Billing/Coding section: CPT code L8679. Diagnosis codes 787.60, 787.61, 787.62, 787.63, 788.20, 788.21, 788.22, 788.29, 788.30, 788.31, 788.32, 788.33, 788.34, 788.35, 788.36, 788.37, 788.38, 788.39. ICD-10 Diagnosis codes R15.9, R15.0, R15.1, R15.2, R33.9, R33.9, R39.14, R33.0, R33.8, R32, N39.41, N39.3, N39.46, N39.42, N39.43, N39.44, N39.45, N39.490, N39.498. Medical Director review 12/2013. (mco)
- 1/28/14 Diagnosis code 788.22 deleted from Billing/Coding section. (mco)
- 5/27/14 Description section updated. Added new clinical condition to the “When Covered” section: “Overactive Bladder”. References updated. (mco)
- 8/26/14 “When Covered” section revised to clarify length of time after surgery trial stimulation can take place. “#2 There is documented failure 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 [or 24 months in case of cancer] previously~~); Added item #6: “The patient has not had rectal surgery in the previous 12 months, or in the case of cancer, the patient has not had rectal surgery in the past 24 months.” References updated. Medical Director review 8/2014. Policy noticed 8/26/14 for effective date 10/28/14. (mco)
- 12/9/14 Specialty Matched Consultant Advisory Panel review 11/24/2014. No change to Policy statements. (sk)
- 9/1/15 Reference added. In both medically necessary statements, period of trial stimulation changed from “at least 1 week” to “at least 48 hours”. (sk)
- 12/30/15 Specialty Matched Consultant Advisory Panel review 11/18/2015. (sk)
- 9/30/16 Codes N39.491 and N39.492 added to Billing/Coding section. (sk)
- 1/27/17 Specialty Matched Consultant Advisory Panel review 11/30/2016. (sk)
- 3/31/17 Reference added. Policy Guidelines updated. ICD-9 codes removed from Billing/Coding section. (sk)
- 12/15/17 Specialty Matched Consultant Advisory Panel review 11/29/2017. (sk)

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

6/8/18 Reference added. (sk)

12/14/18 Specialty Matched Consultant Advisory Panel review 11/28/2018. Biofeedback removed from list of Related Policies. (sk)

7/16/19 Reference added. (sk)

12/10/19 Specialty Matched Consultant Advisory Panel review 11/20/2019. (sk)

8/25/20 Reference added. Expired code 95973 removed from Billing/Coding section. (sk)

5/18/21 Specialty Matched Consultant Advisory Panel review 11/18/2020. (sk)

12/14/21 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 11/17/2021. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.