



Louisiana

Sacral Nerve Neuromodulation/Stimulation

Policy # 00108

Original Effective Date: 03/25/2002

Current Effective Date: 07/13/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Transanal Radiofrequency Treatment of Fecal Incontinence is addressed separately in medical policy 00571.

Note: Percutaneous Tibial Nerve Stimulation is addressed separately in medical policy 00415.

Urinary Incontinence and Non-obstructive Retention

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider a trial period of sacral nerve neuromodulation (SNM) with either percutaneous nerve stimulation or a temporarily implanted lead to be **eligible for coverage****.

Patient Selection Criteria

Coverage eligibility may be considered for a trial period of SNM with either percutaneous nerve stimulation or a temporarily implanted lead in patients who meet ALL of the following criteria:

- There is a diagnosis of at least ONE of the following:
 - Urge incontinence; OR
 - Urgency-frequency syndrome; OR
 - Non-obstructive urinary retention; OR
 - Overactive bladder;

AND

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Louisiana

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Current Effective Date: 07/13/2020

- There is documented failure or intolerance to at least two conventional conservative 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); AND
- The patient is an appropriate surgical candidate; AND
- Incontinence or retention is not related to a neurologic condition (e.g., Parkinson's disease, multiple sclerosis, spinal cord injury).

Based on review of available data, the Company may consider permanent implantation of a sacral nerve neuromodulation (SNM) device to be **eligible for coverage****.

Patient Selection Criteria

Coverage eligibility may be considered for permanent implantation of a SNM device in patients who meet ALL of the following criteria:

- All of the above criteria in the Urinary Incontinence and Non-obstructive Retention section are met, AND
- A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers other urinary/voiding applications of sacral nerve neuromodulation (SNM), including but not limited to treatment of stress incontinence or urge incontinence due to a neurologic condition (eg, detrusor hyperreflexia, multiple sclerosis, spinal cord injury, other types of chronic voiding dysfunction) to be **investigational.***

The use of sacral nerve neuromodulation (SNM) is considered to be **investigational*** when patient selection criteria are not met for the Urinary Incontinence and Non-obstructive Retention coverage section.

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Louisiana

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Fecal Incontinence

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider a trial period of sacral nerve neuromodulation (SNM) with either percutaneous nerve stimulation or a temporarily implanted lead to be **eligible for coverage****.

Patient Selection Criteria

Coverage eligibility may be considered for a trial period of SNM with either percutaneous nerve stimulation or a temporarily implanted lead in patients who meet ALL of the following criteria:

- There is a diagnosis of chronic fecal incontinence of more than 2 incontinent episodes on average per week for more than 6 months or for more than 12 months after vaginal childbirth; AND
- There is documented failure or intolerance to conventional conservative therapy (eg, dietary modification, the addition of bulking and pharmacologic treatment) for at least a sufficient duration to fully assess its efficacy; AND
- The patient is an appropriate surgical candidate; AND
- The condition is not related to an anorectal malformation (eg, congenital anorectal malformation; defects of the external anal sphincter over 60°; visible sequelae of pelvic radiation; active anal abscesses and fistulae) or chronic inflammatory bowel disease; AND
- Incontinence is not related to a neurologic condition; AND
- 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.

Based on review of available data, the Company may consider permanent implantation of a sacral nerve neuromodulation (SNM) device to be **eligible for coverage****.

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Louisiana

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Policy # 00108

Original Effective Date: 03/25/2002

Current Effective Date: 07/13/2020

Patient Selection Criteria

Coverage eligibility may be considered for permanent implantation of a SNM device in patients who meet ALL of the following criteria:

- All of the above criteria in the Fecal Incontinence section are met; AND
- A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers sacral nerve neuromodulation (SNM) in the treatment of chronic constipation or chronic pelvic pain to be **investigational**.*

The use of sacral nerve neuromodulation (SNM) is considered to be **investigational*** when patient selection criteria are not met for the Fecal Incontinence coverage section.

Policy Guidelines

The International Continence Society has defined overactive bladder syndrome as “urinary urgency, usually accompanied by increased daytime frequency and/or nocturia, with urinary incontinence (OAB-wet) or without (OAB-dry), in the absence of urinary tract infection or other detectable disease” (available at <https://www.ics.org/glossary/symptom/overactivebladderoaburgencysyndrome>).

Background/Overview

Treatment

Treatment using sacral nerve neuromodulation, also known as indirect sacral nerve stimulation, is 1 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.

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Louisiana

Sacral Nerve Neuromodulation/Stimulation

Policy # 00108

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Current Effective Date: 07/13/2020

The sacral nerve neuromodulation 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, kept by the patient, is 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.

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. 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. 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 ways. They include its use instead of percutaneous nerve evaluation, for patients who failed percutaneous nerve evaluation, for patients with an inconclusive percutaneous nerve evaluation, or for patients who had a successful percutaneous nerve evaluation to refine patient selection further.

The permanent device is implanted with the patient under general anesthesia. The electrical leads are placed in contact with the sacral nerve root(s) via an incision in the lower back, and 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 on and off by placing the control magnet over the area of the pulse generator for 1 to 2 seconds.

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Louisiana

Sacral Nerve Neuromodulation/Stimulation

Policy # 00108

Original Effective Date: 03/25/2002

Current Effective Date: 07/13/2020

This evidence review does not address pelvic floor stimulation, which refers to electrical stimulation of the pudendal nerve. Also, this review does not address devices that provide direct sacral nerve stimulation in patients with spinal cord injuries.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 1997, the InterStim[®]‡ Sacral Nerve Stimulation system (Medtronic) was approved by the U.S. FDA through the premarket approval process for the indication of urinary urge incontinence in patients who have failed or could not tolerate more conservative treatments. In 1999, the device received the FDA approval for the additional indications of urgency-frequency and urinary retention in patients without mechanical obstruction. In 2006, the InterStim II[®]‡ System (Medtronic) was approved by the FDA through the premarket approval process for treatment of intractable cases of overactive bladder and urinary retention. The new device is smaller and lighter than the original 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 InterStim System was approved by the FDA through the premarket approval process 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 the FDA for treatment of chronic pelvic pain.

FDA product code: EZW.

Axonics Sacral Neuromodulation System was FDA approved in 2019.

The Axonics Sacral Neuromodulation (SNM) System is a sacral nerve stimulation (SNS) system that is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments. It is also intended to treat urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more

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Louisiana

Sacral Nerve Neuromodulation/Stimulation

Policy # 00108

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conservative treatments. It uses an implanted stimulator to deliver electrical pulses through a lead wire to electrodes located near the sacral nerve.

Rationale/Source

Sacral nerve neuromodulation, also known as sacral nerve stimulation, involves the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. This evidence review addresses the use of sacral nerve neuromodulation to treat urinary or fecal incontinence, fecal nonobstructive retention, and chronic pelvic pain in patients with intact neural innervation of the bladder and/or rectum.

For individuals with urinary incontinence who have failed conservative treatment who receive sacral nerve neuromodulation, the evidence includes randomized controlled trials (RCTs), systematic reviews, 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 sacral nerve neuromodulation 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 a meaningful improvement in the net health outcome.

For individuals with fecal incontinence who have failed conservative treatment who receive sacral nerve neuromodulation, the evidence includes RCTs and systematic reviews. 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. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with constipation who have failed conservative treatment who receive sacral nerve neuromodulation, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, and treatment, related morbidity. The available trials have not consistently reported improvements in outcomes with sacral nerve neuromodulation. Additional studies are needed to demonstrate the health benefits of this technology. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Louisiana

Sacral Nerve Neuromodulation/Stimulation

Policy # 00108

Original Effective Date: 03/25/2002

Current Effective Date: 07/13/2020

For individuals with chronic pelvic pain who receive sacral nerve neuromodulation, the evidence is limited to case series. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 4 physician specialty societies and 2 academic medical centers while this policy was under review in 2012. Reviewers from two specialty societies and two academic medical centers provided opinions on the possible medical necessity of implantable leads for test stimulation, as part of a 2-stage process for device implantation. All four respondents supported the use of implantable leads for test stimulation as an alternative to percutaneous test stimulation, for patients who had failed percutaneous test stimulation and/or for patients with inconclusive percutaneous test stimulation. Reasons for support included a longer period of interrupted treatment with stage-1 stimulation due to less lead migration and a higher rate of positive tests compared with percutaneous test stimulation.

Practice Guidelines and Position Statements

Urinary Disorders

American Urological Association

In 2019, the American Urological Association updated its guidelines on the diagnosis and treatment of overactive bladder. The guidelines stated that sacral neuromodulation may be offered as a third-line treatment in carefully selected patients with severe refractory symptoms or into those who are not candidates for second-line therapy (eg, oral antimuscarinics, oral β 3-adrenoceptor agonists, transdermal oxybutynin) and are willing to undergo surgery (recommendation, evidence strength grade C).

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Louisiana

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American College of Obstetricians and Gynecologists

A 2015 practice bulletin on urinary incontinence (replaced practice bulletin number 63, 2005; reaffirmed in 2018) from the College stated, "sacral neuromodulation may be considered for patients with recalcitrant urinary urge incontinence who have failed other conservative measures, including bladder training, pelvic floor physical therapy with biofeedback, and pharmacologic treatment."

Fecal Disorders

National Institute for Health and Care Excellence

In 2007, the National Institute for Health and Care Excellence issued guidance on the management of fecal incontinence. The guidance was reviewed in 2014 and 2018, and no changes were made.

The guidance has recommended:

"a trial of temporary sacral nerve stimulation should be considered for people with fecal incontinence in whom sphincter surgery is deemed inappropriate.... All individuals should be informed of the potential benefits and limitations of this procedure and should undergo a trial stimulation period of at least 2 weeks to determine if they are likely to benefit. People with fecal incontinence should be offered sacral nerve stimulation on the basis of their response to percutaneous nerve evaluation during specialist assessment, which is predictive of therapy success."

American College of Gastroenterology

In its 2014 clinical guideline on the management of benign anorectal disorders, including fecal incontinence, the American College of Gastroenterology found that "sacral nerve stimulation should be considered in [fecal incontinence] who do not respond to conservative therapy (strong recommendation, moderate quality of evidence)."

Pelvic Floor Society

In 2017, the Pelvic Floor Society conducted a systematic review as the basis for practice recommendations on the use of sacral nerve stimulation for the treatment of constipation. The systematic review assessed 7 observational studies, all generally of poor quality due to inadequate description of methods. Due to inconsistent reporting on harms and treatment success, and heterogeneity in the patient populations, the Society could not recommend sacral nerve stimulation.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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Medicare National Coverage

In 2002, the Centers for Medicare & Medicaid Services covers sacral nerve stimulation 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.”

“The following limitations for coverage apply to all three indications:

- Patients must be refractory to conventional therapy ... and be appropriate surgical candidates such that implantation with anesthesia can occur.
- Patients with stress incontinence, urinary obstruction, and specific neurologic diseases ... that are associated with secondary manifestations ... are excluded.
- Patients must have had successful test stimulation in order to support subsequent implantation. Before patients are eligible for permanent implantation, they must demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through voiding diaries.”

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02434874 ^a	Sacral Nerve Stimulation to Treat Urgency Urinary Incontinence with Wireless Neuromodulation	60	Dec 2022
NCT03261622	Sacral Nerve Stimulation for Fecal Incontinence - Placebo or Clinical Effective (SNS)	75	Nov 2020
NCT03139734	Sacral Neuromodulation for Pelvic Pain Associated with Endometriosis	50	May 2022

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Louisiana

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NCT03811821	Comparative Effects of Biofeedback, Sacral Nerve Stimulation, and Injectable Bulking Agents for Treatment of Fecal Incontinence: The Fecal Incontinence Treatment Study (FIT) Study	569	Mar 2023
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^a denotes an industry-sponsored trial
NCT: national clinical trial.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Sacral Nerve Modulation/Stimulation”, Policy 7.01.69, May 2020.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Sacral nerve stimulation for the treatment of urge incontinence. TEC Assessments 1998;Volume 13:Tab 18.
3. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Sacral nerve stimulation for the treatment of refractory urinary urgency/frequency in adults. TEC Assessments. 2000;Volume 15:Tab 7.
4. Food and Drug Administration (FDA). Summary of Safety and Effectiveness: Medtronic Interstim System for Urinary Control. http://www.accessdata.fda.gov/cdrh_docs/pdf/P970004S004b.pdf.
5. 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. Feb 2000;37(2):161-171. PMID 10705194.
6. Siegel S, Noblett K, Mangel J, 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. Mar 2015;34(3):224-230. PMID 24415559.
7. Noblett K, Siegel S, Mangel J, 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. Feb 2016;35(2):246-251. PMID 25546568.
8. Amundsen CL, Richter HE, Menefee SA, et al. OnabotulinumtoxinA vs sacral neuromodulation on refractory urgency urinary incontinence in women: a randomized clinical trial. JAMA. Oct 04 2016;316(13):1366-1374. PMID 27701661.

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9. Groen J, Blok BF, Bosch JL. Sacral neuromodulation as treatment for refractory idiopathic urge urinary incontinence: 5-year results of a longitudinal study in 60 women. *J Urol.* Sep 2011;186(3):954-959. PMID 21791355.
10. White WM, Mobley JD, 3rd, Doggweiler R, et al. Incidence and predictors of complications with sacral neuromodulation. *Urology.* Apr 2009;73(4):731-735. PMID 19193415.
11. Thaha MA, Abukar AA, Thin NN, et al. Sacral nerve stimulation for faecal incontinence and constipation in adults. *Cochrane Database Syst Rev.* Aug 24 2015(8):CD004464. PMID 26299888.
12. Thin NN, Horrocks EJ, Hotouras A, et al. Systematic review of the clinical effectiveness of neuromodulation in the treatment of faecal incontinence. *Br J Surg.* Oct 2013;100(11):1430-1447. PMID 24037562.
13. 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.* Mar 2011;26(3):275-294. PMID 21279370.
14. Maeda Y, Matzel K, Lundby L, et al. Postoperative issues of sacral nerve stimulation for fecal incontinence and constipation: a systematic literature review and treatment guideline. *Dis Colon Rectum.* Nov 2011;54(11):1443-1460. PMID 21979192.
15. 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.* May 2008;51(5):494-502. PMID 18278532.
16. 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.* Nov 2005;242(5):662-669. PMID 16244539.
17. Wexner SD, Collier JA, Devroede G, et al. Sacral nerve stimulation for fecal incontinence: results of a 120-patient prospective multicenter study. *Ann Surg.* Mar 2010;251(3):441-449. PMID 20160636.
18. Mellgren A, Wexner SD, Collier JA, et al. Long-term efficacy and safety of sacral nerve stimulation for fecal incontinence. *Dis Colon Rectum.* Sep 2011;54(9):1065-1075. PMID 21825885.
19. Hull T, Giese C, Wexner SD, et al. Long-term durability of sacral nerve stimulation therapy for chronic fecal incontinence. *Dis Colon Rectum.* Feb 2013;56(2):234-245. PMID 23303153.
20. Altomare DF, Giuratrabocchetta S, Knowles CH, et al. Long-term outcomes of sacral nerve stimulation for faecal incontinence. *Br J Surg.* Mar 2015;102(4):407-415. PMID 25644687.

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21. Thomas GP, Dudding TC, Rahbour G, et al. Sacral nerve stimulation for constipation. *Br J Surg.* Jan 2013;100(2):174-181. PMID 23124687.
22. Knowles CH, Thin N, Gill K, et al. Prospective randomized double-blind study of temporary sacral nerve stimulation in patients with rectal evacuatory dysfunction and rectal hyposensitivity. *Ann Surg.* Apr 2012;255(4):643-649. PMID 22418005.
23. Dinning PG, Hunt L, Patton V, et al. Treatment efficacy of sacral nerve stimulation in slow transit constipation: a two-phase, double-blind randomized controlled crossover study. *Am J Gastroenterol.* May 2015;110(5):733-740. PMID 25895520.
24. Kamm MA, Dudding TC, Melenhorst J, et al. Sacral nerve stimulation for intractable constipation. *Gut.* Mar 2010;59(3):333-340. PMID 20207638.
25. Maeda Y, Lundby L, Buntzen S, et al. Sacral nerve stimulation for constipation: suboptimal outcome and adverse events. *Dis Colon Rectum.* Jul 2010;53(7):995-999. PMID 20551750.
26. Tirlapur SA, Vlismas A, Ball E, et al. Nerve stimulation for chronic pelvic pain and bladder pain syndrome: a systematic review. *Acta Obstet Gynecol Scand.* Aug 2013;92(8):881-887. PMID 23710833.
27. Martellucci J, Naldini G, Carriero A. Sacral nerve modulation in the treatment of chronic pelvic pain. *Int J Colorectal Dis.* Jul 2012;27(7):921-926. PMID 22203519.
28. Siegel S, Paszkiewicz E, Kirkpatrick C, et al. Sacral nerve stimulation in patients with chronic intractable pelvic pain. *J Urol.* Nov 2001;166(5):1742-1745. PMID 11586214.
29. Baxter C, Kim JH. Contrasting the percutaneous nerve evaluation versus staged implantation in sacral neuromodulation. *Curr Urol Rep.* Sep 2010;11(5):310-314. PMID 20535593.
30. Leong RK, De Wachter SG, Nieman FH, et al. PNE versus 1st stage tined lead procedure: a direct comparison to select the most sensitive test method to identify patients suitable for sacral neuromodulation therapy. *Neurourol Urodyn.* Sep 2011;30(7):1249-1252. PMID 21404317.
31. Scheepens WA, Van Koevinge GA, De Bie RA, et al. Long-term efficacy and safety results of the two-stage implantation technique in sacral neuromodulation. *BJU Int.* Dec 2002;90(9):840-845. PMID 12460343.
32. Marcelissen TA, Leong RK, de Bie RA, et al. Long-term results of sacral neuromodulation with the tined lead procedure. *J Urol.* Nov 2010;184(5):1997-2000. PMID 20850820.
33. Borawski KM, Foster RT, Webster GD, et al. Predicting implantation with a neuromodulator using two different test stimulation techniques: A prospective randomized study in urge incontinent women. *Neurourol Urodyn.* Nov 2007;26(1):14-18. PMID 17123297.

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Sacral Nerve Neuromodulation/Stimulation

Policy # 00108

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Current Effective Date: 07/13/2020

34. Bannowsky A, Wefer B, Braun PM, et al. Urodynamic changes and response rates in patients treated with permanent electrodes compared to conventional wire electrodes in the peripheral nerve evaluation test. *World J Urol.* Dec 2008;26(6):623-626. PMID 18629503.
35. Gormley EA, Lightner DJ, Faraday M, et al. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline Amendment. *J Urol.* May 2015;193(5):1572-1580. PMID 25623739.
36. American College of Obstetricians and Gynecologists. Urinary incontinence in women. *Obstet Gynecol.* Jun 2005;105(6):1533-1545. PMID 15932869.
37. ACOG Practice Bulletin No. 155: Urinary Incontinence in Women. *Obstet Gynecol.* Nov 2015;126(5):e66-81. PMID 26488524.
38. National Institute for Health and Care Excellence (NICE). Faecal incontinence in adults: management [CG49]. 2007; <https://www.nice.org.uk/guidance/CG49>.
39. Wald A, Bharucha AE, Cosman BC, et al. ACG clinical guideline: management of benign anorectal disorders. *Am J Gastroenterol.* 2014 Aug;109(8):1141-57; (Quiz) 1058. PMID: 25022811.
40. Pilkington SA, Emmett C, Knowles CH, et al. Surgery for constipation: systematic review and practice recommendations: Results V: Sacral Nerve Stimulation. *Colorectal Dis.* Sep 2017;19(Suppl 3):92-100. PMID 28960926.
41. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for SACRAL NERVE Stimulation For Urinary Incontinence (230.18). 2002; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=249&ncdver=1&CoverageSelection=National&KeyWord=sacral+nerve&KeyWordLookUp=Title&KeywordSearchType=And&clickon=search&bc=gAAAABAAAAAAA%3d%3d&>
42. Food and Drug Administration (FDA). Axonics Sacral Neuromodulation System. September 2019. https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190006a.pdf

Policy History

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03/21/2002 Medical Policy Committee review

03/25/2002 Managed Care Advisory Council approval

06/24/2002 Format revision. No substance change to policy.

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Louisiana

Sacral Nerve Neuromodulation/Stimulation

Policy # 00108

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Current Effective Date: 07/13/2020

10/05/2004	Medical Director review
11/16/2004	Medical Policy Committee review. Format revision. Policy focus expanded to include other pelvic floor dysfunction conditions in addition to urinary incontinence.
11/29/2004	Managed Care Advisory Council approval
10/05/2005	Medical Director review
10/18/2005	Medical Policy Committee review. Format revision. FDA approval information added. Coverage eligibility unchanged.
10/27/2005	Quality Care Advisory Council approval
10/04/2006	Medical Director review
10/18/2006	Medical Policy Committee approval. Format revision; updated with additional references. Coverage eligibility unchanged.
09/05/2007	Medical Director review
09/19/2007	Medical Policy Committee approval. Coverage eligibility unchanged.
09/09/2008	Medical Director review
09/17/2008	Medical Policy Committee approval. Coverage eligibility unchanged. A note stating that a successful trial response to a peripheral nerve stimulation test is required prior to permanent placement under general anesthesia.
06/04/2009	Medical Director review
06/17/2009	Medical Policy Committee approval. Coverage eligibility unchanged.
06/03/2010	Medical Policy Committee approval
06/16/2010	Medical Policy Implementation Committee approval. Added criteria for SNM for the treatment of patients with urge incontinence, urgency-frequency and non-obstructive urinary retention to be eligible for coverage as follows: <ul style="list-style-type: none">• The patient is an appropriate surgical candidate; and• A successful percutaneous test stimulation, defined as at least 50% improvement in symptoms, was performed. Change coverage for fecal incontinence from investigational to eligible for coverage with criteria.
06/02/2011	Medical Policy Committee review
06/15/2011	Medical Policy Implementation Committee approval. Format revision; including, addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
06/14/2012	Medical Policy Committee review
06/20/2012	Medical Policy Implementation Committee approval. No change to coverage.

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- 06/06/2013 Medical Policy Committee review
- 06/25/2013 Medical Policy Implementation Committee approval. Title changed. “For Pelvic Floor” dropped. Criteria revised.
- 06/05/2014 Medical Policy Committee review
- 06/18/2014 Medical Policy Implementation Committee approval. No change to coverage.
- 06/04/2015 Medical Policy Committee review
- 06/17/2015 Medical Policy Implementation Committee approval. Added overactive bladder to criteria section of eligibility statement.
- 08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
- 06/02/2016 Medical Policy Committee review
- 06/20/2016 Medical Policy Implementation Committee approval. Period of trial stimulation changed to “at least 48 hours”. 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 was added to the fecal incontinence criteria.
- 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
- 06/01/2017 Medical Policy Committee review
- 06/21/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 06/07/2018 Medical Policy Committee review
- 06/20/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 06/06/2019 Medical Policy Committee review
- 06/19/2019 Medical Policy Implementation Committee approval. Added “or retention” to differentiate incontinence “or” retention. Neurologic condition examples added (e.g., Parkinson’s disease, multiple sclerosis, spinal cord injury) to the Urinary Incontinence and Non-obstructive Retention section. Clarified coverage sections in the criteria bullets. Added two investigational statements to address when patient selection criteria are not met.
- 06/04/2020 Medical Policy Committee review
- 06/10/2020 Medical Policy Implementation Committee approval. No change to coverage. New FDA information added.
- 09/24/2020 Coding update
- Next Scheduled Review Date: 06/2021

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	64561, 64581, 64585, 64590, 64595, 95970, 95971, 95972
HCPCS	A4290, C1767, C1778, C1816, C1820, C1883, C1897, E0745, L8680, L8685, L8686, L8687, L8688, L8689
ICD-10 Diagnosis	N39.3, N39.41-N39.46, N39.490, N39.498, R15.0-R15.9, R32, R33.0-R33.9, R39.14

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***Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

****Medically Necessary** (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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