Sacral Nerve Neuromodulation/Stimulation

Policy # 00108
Original Effective Date: 03/25/2002
Current Effective Date: 07/08/2024

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 individuals 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

- 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 individual 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 individuals 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.

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 individuals 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 individual 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 individual 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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Patient Selection Criteria
Coverage eligibility may be considered for permanent implantation of a SNM device in individuals 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 individuals 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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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 individuals, 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, individuals 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 individuals are appropriate candidates for the permanent device. If individuals 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 individuals 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 individuals who failed percutaneous nerve evaluation, for with an inconclusive percutaneous nerve evaluation, or for individuals who had a successful percutaneous nerve evaluation to refine individual selection further.

The permanent device is implanted with the individuals 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 individual. The individual 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.

This evidence review does not address pelvic floor stimulation, which refers to electrical stimulation of the pudendal nerve. Pelvic floor stimulation is addressed separately. Also, this review does not address devices that provide direct sacral nerve stimulation in individuals 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. Food and Drug Administration (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 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 the 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 both fecal incontinence, chronic fecal incontinence in patients who have failed or could not tolerate more conservative treatments.

In 2020, the InterStim X™‡ device was approved by the FDA. This latest generation of the InterStim device does not require recharging and has a battery life of at least 10 years and up to 15 years if used at a low-energy setting.

The InterStim device has not been specifically approved by the FDA for the treatment of chronic pelvic pain.

In 2019, the Axonics®‡ Sacral Neuromodulation System (Axonics) received premarket approval from the FDA for both fecal incontinence and treatment of urinary retention and symptoms of overactive bladder. This system has a rechargeable battery that has a device life of 15 years after implantation.

In 2023, the Virtis™‡ Sacral Neuromodulation System (Nuvectra) was approved by the FDA for treatment of urinary retention and symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency in patients who have failed more conservative treatments.

FDA product code: EZW.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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.

Summary of Evidence - Intro

For individuals with urinary incontinence who have failed conservative treatment who receive sacral nerve neuromodulation, 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 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 an 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, 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 sacral nerve neuromodulation, 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 sacral nerve neuromodulation. 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 sacral nerve neuromodulation, the evidence is limited to systematic reviews of 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.

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.

2012 Input

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 2 specialty societies and 2 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 4 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
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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 in those who are not candidates for second-line therapy (eg, oral antimuscarinics, oral β3-adrenoceptor agonists, transdermal oxybutynin) and are willing to undergo surgery (recommendation, evidence strength Grade C).

American College of Obstetricians and Gynecologists
A 2015 practice bulletin on urinary incontinence (replaced practice bulletin number 63, 2005; reaffirmed in 2019) 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."

International Continence Society
In 2018, the International Continence Society published a best practice statement on the use of sacral neuromodulation. The authors specified that the guideline recommendations applied primarily to the Interstim device and may or may not be applicable to future devices that have become available since that time. For both urinary and bowel disorders, first-line interventions include behavioral therapy, physical therapy, and medical management. Sacral neuromodulation can be offered to patients who fail or have an intolerance to first-line interventions. The guideline also states that sacral neuromodulation is appropriate for interstitial cystitis, bladder pain syndrome, Fowler's syndrome, voiding dysfunction, and nonobstructive urinary retention. However, there was a lack of evidence

supporting the use of sacral neuromodulation for chronic pelvic pain unrelated to any of the aforementioned etiologies. For constipation, sacral neuromodulation should only be considered for patients who have had symptoms for at least 1 year, whose symptoms cannot be attributed to a mechanically correctable cause, and when conservative treatment has failed. Contraindications to sacral neuromodulation include lack of response during a therapeutic trial and pregnancy. Relative contraindications may include severe or rapidly progressive neurologic disease, abnormal sacral anatomy, anticipated need for magnetic resonance imaging below the head, and spinal cord injury.

National Institute for Health and Care Excellence
In 2020, NICE issued guidance on the Axonics sacral neuromodulation system for treating refractory overactive bladder. The guidance states that the Axonics system should be considered an option for people with refractory overactive bladder. Similarly, 2004 guidance states that use of sacral nerve stimulation for urge incontinence and symptoms of urgency/frequency is supported by evidence of efficacy and safety.

Fecal Disorders
National Institute for Health and Care Excellence
In 2007, NICE 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 (ACG) found that "sacral nerve stimulation should be considered in [fecal incontinence] who do not respond to conservative therapy (strong recommendation, moderate quality of evidence)." The 2021 update of these guidelines keep the recommendation for sacral nerve stimulation in patients with fecal incontinence refractory to medical therapy the same as in the 2014 version. Additionally, due to a lack of evidence supporting efficacy and the risk of adverse events and complications, the 2021 ACG Panel makes a statement

stating that sacral nerve stimulation "cannot be recommended in patients with constipation of any type."

American College of Obstetricians and Gynecologists
A 2019 practice bulletin (reaffirmed 2021) on fecal incontinence from the American College of Obstetricians and Gynecologists (ACOG) stated, "Sacral nerve stimulation can be considered as a surgical treatment option for women with fecal incontinence with or without anal sphincter disruption who have failed conservative treatments."

American Society of Colon and Rectal Surgeons
In 2023, the American Society of Colon and Rectal Surgeons released an updated clinical practice guideline for the treatment of fecal incontinence. They stated that "sacral neuromodulation may be considered as a first-line surgical option for incontinent patients with and without sphincter defects (strength of recommendation, conditional; GRADE quality of evidence, low)."

In 2016, the Society released a clinical practice guideline for the management of constipation. In this guideline, they stated "sacral neuromodulation may be an effective treatment for patients with chronic constipation and successful peripheral nerve evaluation test when conservative measures have failed; however, it is not currently approved by the US Food and Drug Administration for this condition in the United States (Grade of Recommendation: Weak, based on moderate quality evidence, 2B)."

Chronic Pelvic Pain
American College of Obstetricians and Gynecologists
A 2020 practice bulletin (reaffirmed 2023) on chronic pelvic pain from ACOG does not mention sacral nerve stimulation or modulation.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
Since 2002, the Centers for Medicare & Medicaid Services has covered 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
Ongoing			
NCT03811821	Comparative Effects of Biofeedback, Sacral Nerve Stimulation, and Injectable Bulking Agents for Treatment of Fecal Incontinence: The Fecal Incontinence Treatment Study (FIT) Study	271	Dec 2025
NCT04713085	Sacral Nerve Stimulation in Children and Adolescents With Chronic Constipation: a Case-control Study on Invasive and Non-invasive Neuromodulatory Treatment	30	Dec 2023
NCT04232696[a]	Clinical Study of Neuaspera's Implantable Sacral Nerve Stimulation (SNS) System in Patients With Symptoms of Overactive Bladder (OAB)	310	April 2024

NCT02577302[a]	Multi-center, Prospective, Randomized, Controlled, Non-Inferiority, Clinical Trial of Chronic Afferent Nerve Stimulation (CAN-Stim) of the Tibial Nerve Versus Sacral Nerve Stimulation (SNS) in the Treatment of Urinary Urgency Incontinence Resulting From Refractory Overactive Bladder (OAB)	200	Oct 2025
NCT05543382[a]	Cycling Study With the Axonics System	60	Feb 2024
NCT05064384[a]	Axonics Sacral Neuromodulation System Registry Study : ARTISTRY	300	Nov 2023
Unpublished			
NCT04710433	Non-invasive Sacral Nerve Stimulation in Children and Adolescents With Chronic Constipation: a Case-control Study on External Neuromodulatory Treatment	59	Dec 2021

[a] denotes an industry-sponsored trial
NCT: national clinical trial.

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Policy History

Original Effective Date: 03/25/2002
Current Effective Date: 07/08/2024

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.
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:
- 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.
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.
06/03/2021	Medical Policy Committee review
06/09/2021	Medical Policy Implementation Committee approval. No change to coverage.
06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. No change to coverage.
06/01/2023	Medical Policy Committee review
06/14/2023	Medical Policy Implementation Committee approval. No change to coverage.
06/06/2024	Medical Policy Committee review
06/12/2024	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 06/2025

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 2023 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.

Sacral Nerve Neuromodulation/Stimulation

Policy # 00108
Original Effective Date: 03/25/2002
Current Effective Date: 07/08/2024

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

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	All related Diagnoses

*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 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.

Sacral Nerve Neuromodulation/Stimulation

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NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.