LOUISIANA BLUE

# Sacral Nerve Neuromodulation/Stimulation

**Policy # 00108**
Original Effective Date: 03/25/2002
Current Effective Date: 07/01/2025

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

# 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****.

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).

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# 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.

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 medical policy 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 regulations, other plan medical policies, and accredited national guidelines.

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**Description**
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 medical policy addresses the use of sacral nerve neuromodulation to treat urinary or fecal incontinence, fecal nonobstructive retention, and chronic pelvic pain in individuals 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.

**Additional Information**
Not applicable.

# 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 2024 the American Urological Association updated its guidelines on the diagnosis and treatment of overactive bladder. The guidelines stated that "In patients with OAB who have an inadequate response to, or have experienced intolerable side effects from, pharmacotherapy or behavioral therapy, clinicians should offer sacral neuromodulation, tibial nerve stimulation, and/or intradetrusor botulinum toxin injection. (Moderate Recommendation; Evidence Level: Grade A)".

**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 faecal 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 faecal 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)". In 2024, the Society released guidelines for the evaluation and management of chronic constipation. Sacral neuromodulation was not mentioned in these guidelines.

**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 2024 |
| NCT04232696[a] | Clinical Study of Neuaspera's Implantable Sacral Nerve Stimulation (SNS) System in Patients With Symptoms of Overactive Bladder (OAB) | 242 | Dec 2026 |
| 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 | Dec 2024 |
| *Unpublished* | | | |
| NCT05064384[a] | Axonics SacRal NeuromodulaTIon System RegisTRY Study : ARTISTRY | 272 | Oct 2023 |
| NCT04710433 | Non-invasive Sacral Nerve Stimulation in Children and Adolescents With Chronic | 59 | Dec 2021 |

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|---|---|---|---|
| | Constipation: a Case-control Study on External Neuromodulatory Treatment | | |

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# Policy History

Original Effective Date: 03/25/2002
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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. |
| 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:<br>• The patient is an appropriate surgical candidate; and<br>• A successful percutaneous test stimulation, defined as at least 50% improvement in symptoms, was performed.<br>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. |

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|---|---|
| 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. |
| 06/05/2025 | Medical Policy Committee review |
| 06/11/2025 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |

Next Scheduled Review Date: 06/2026

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# Coding

*The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 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.*

*The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue 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 Louisiana Blue 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 Louisiana Blue 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.

**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.