MEDICAL POLICY

POLICY TITLE	SACRAL NERVE NEUROMODULATION/STIMULATION AND PELVIC FLOOR STIMULATION DEVICES
POLICY NUMBER	MP 1.033

Effective Date:	1/1/2024

I. POLICY

Sacral Nerve Neuromodulation/Stimulation

Urinary Incontinence and Non-obstructive Retention

A. A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered **medically necessary** in members who meet all the following criteria:
   - There is a diagnosis of at least one of the following:
     - Urge incontinence
     - Urgency-frequency syndrome
     - Non-obstructive urinary retention
     - Overactive bladder
   - 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).
     - The member is an appropriate surgical candidate.
     - Incontinence is not related to a neurologic condition.

B. Permanent implantation of a sacral nerve neuromodulation device may be considered **medically necessary** in members who meet all the following criteria:
   - All of criteria in A. above are met.
   - A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

Other urinary/voiding applications of sacral nerve neuromodulation are considered **investigational**, including but not limited to treatment of stress incontinence or urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia, multiple sclerosis, spinal cord injury, or other types of chronic voiding dysfunction). There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Fecal Incontinence

A. A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered **medically necessary** in members who meet all the following criteria:

- There is a diagnosis of chronic fecal incontinence of greater than two (2) incontinent episodes on average per week with duration greater than six (6) months or for more than 12 months after vaginal childbirth.
- There is documented failure or intolerance to conventional conservative therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment) for at least a sufficient duration to fully assess its efficacy.
- The member is an appropriate surgical candidate.
- The condition is not related to an anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae) or chronic inflammatory bowel disease.
- Incontinence is not related to a neurologic condition.
- The member has not had rectal surgery in the previous 12 months or, in the case of cancer, the member has not had rectal surgery in the past 24 months.

B. Permanent implantation of a sacral nerve neuromodulation device may be considered **medically necessary** in patients who meet all the following criteria:
   - All of criteria in A. above are met.
   - A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

Sacral nerve neuromodulation is **investigational** in the treatment of chronic constipation or chronic pelvic pain. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Pelvic Floor Stimulation

Non- invasive *electrical* pelvic floor stimulation devices for the treatment of stress and/or urge urinary incontinence may be considered **medically necessary** when the following criteria are met:

- The member is cognitively intact;
- The member has failed a documented trial of pelvic muscle exercise (PME) training*.

***Note**: A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.

Non-invasive *electrical* stimulator devices used for the treatment of fecal incontinence are considered **investigational.**

Non-invasive *magnetic* pelvic stimulator devices used for the treatment of urinary and fecal incontinence are considered **investigational.**

There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures.

Policy Guidelines

The International Continence Society has defined overactive bladder syndrome (OAB) 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).

Cross-references:

MP 1.134 Percutaneous Tibial Nerve Stimulation
MP 2.064 Biofeedback and Neurofeedback Therapy

II. PRODUCT VARIATIONS Top

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND Top

Sacral Nerve Neuromodulation/Stimulation

Urinary and Fecal Incontinence

Urge incontinence is defined as leakage of urine when there is a strong urge to void. Urgency-frequency is an uncontrollable urge to urinate, resulting in very frequent, small volumes and is a prominent symptom of interstitial cystitis (also called bladder pain syndrome). Urinary retention is the inability to empty the bladder of urine completely. Fecal incontinence can arise from a variety of mechanisms, including rectal wall compliance, efferent and afferent neural pathways, central and peripheral nervous systems, and voluntary and involuntary muscles. Fecal incontinence is more common in women, due mainly to muscular and neural damage that may occur during vaginal delivery.

Treatment

Treatment using sacral nerve neuromodulation, also known as indirect sacral nerve stimulation, is one of several alternative modalities for patients with urinary or fecal incontinence (urge incontinence, significant symptoms of urgency-frequency, nonobstructive urinary retention) who have failed behavioral (e.g., 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 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 (PNE). This procedure is done with the patient under local anesthesia, using a test needle to identify the appropriate sacral nerve(s). Once identified, a temporary wire lead is inserted through the test needle and left in place for 4 to 7 days. This lead is connected to an external stimulator, which is carried by patients in their pocket or on their belt. 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 PNE, for patients who failed PNE, for patients with an inconclusive PNE, or for patients who had a successful PNE 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.

This review does not address devices that provide direct sacral nerve stimulation in patients with spinal cord injuries.

Regulatory Status

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 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 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 FDA for treatment of chronic pelvic pain.

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.

Pelvic Floor Stimulation

Incontinence

Incontinence, especially urinary, is a common condition and can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that, among noninstitutionalized persons 65 years of age and older, 44% have reported issues with urinary incontinence. Urinary incontinence in women is common, with some estimates citing a 50% incidence. Factors that increase a woman's risk include older age, obesity, parity, vaginal delivery, and family history.

Urinary incontinence is less common in men, with estimates ranging from 11% to 34% in men greater than 65 years. Factors that increase a man's risk include older age, prostate disease, urinary tract infection history, impaired activities of daily living, neurologic disease, constipation, diabetes, and sleep apnea.

Treatment

Nonsurgical treatment options for incontinence may include pharmacologic therapy, pelvic floor muscle exercises, bowel or bladder training exercises, electrical stimulation, and neuromodulation.

Pelvic Floor Stimulation

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Pelvic floor stimulation (PFS) involves electrical stimulation of pelvic floor muscles using either a probe wired to a device for controlling the electrical stimulation or, more recently, extracorporeal electromagnetic (also called magnetic) pulses. Stimulation of the pudendal nerve to activate the pelvic floor musculature may improve urethral closure. In addition, PFS is thought to improve partially denervated urethral and pelvic floor musculature by enhancing the process of reinnervation. Methods of electrical PFS have varied in location (e.g., vaginal, rectal), stimulus frequency, stimulus intensity or amplitude, pulse duration, pulse to rest ratio, treatments per day, number of treatment days per week, length of time for each treatment session, and overall time period for device use between clinical and home settings. Variations in the amplitude and frequency of the electrical pulse are used to mimic and stimulate the different physiologic mechanisms of the voiding response, depending on the etiology of the incontinence (e.g., either detrusor instability, stress incontinence, or a mixed pattern). Magnetic PFS does not require an internal electrode; instead, patients sit fully clothed on a specialized chair with an embedded magnet.

Patients receiving electrical PFS may undergo treatment in a physician's office or physical therapy facility, or patients may undergo initial training in a physician's office followed by home treatment with a rented or purchased pelvic floor stimulator. Magnetic PFS may be administered in the physician's office.

Regulatory Status

Several electrical stimulators have been cleared by the U.S. Food and Drug Administration (FDA). In 2006, the MyoTrac Infiniti™ (Thought Technology) and in 2015, the ApexM (InControl Medical), nonimplanted electrical stimulators for treating urinary incontinence, were cleared for marketing by FDA through the 510(k) process. Predicate devices also used to treat urinary incontinence, include the Pathway™ CTS 2000 (Prometheus Group) and the InCare® PRS (Hollister). In 2011, the itouch Sure Pelvic Floor Exerciser (TensCare) was cleared for marketing. This product is being marketed in the United States as EmbaGYN® (Everett Laboratories).

In 2000, the NeoControl® Pelvic Floor Therapy System (Neotonus) cleared through the FDA 510(k) process for treating urinary incontinence in women. This device, formerly known as the Neotonus Model 1000 Magnetic Stimulator, provides noninvasive electromagnetic stimulation of pelvic floor musculature. The magnetic system is embedded in a chair seat; patients sit on the chair fully clothed and receive the treatment. The magnetic fields are controlled by a separate power unit.

In 2014, the InTone®MV (InControl Medical), a nonimplantable device that provides electrical stimulation and/or biofeedback via manometry, was cleared by FDA. The device is intended to treat male and female urinary and fecal incontinence.

FDA product code: KPI.

IV. RATIONALE

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Sacral Nerve Neuromodulation/Stimulation

Summary of Evidence
For individuals with urinary incontinence who have failed conservative treatment who receive SNM, the evidence includes 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 SNM reduces symptoms of urge incontinence, urgency-frequency syndrome, nonobstructive urinary retention, and overactive bladder in selected patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with fecal incontinence who have failed conservative treatment who receive SNM, 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 SNM, 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 SNM. 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.

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

Pelvic Floor Stimulation

Summary of Evidence
For individuals who have urinary incontinence who receive electrical PFS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Findings from multiple RCTs have not found that electrical PFS used to treat urinary incontinence in women consistently improves the net health outcome compared with placebo or other conservative treatments. Meta-analyses of these RCTs have also reported inconsistent findings. Moreover, meta-analyses of RCTs have not found a significant benefit of electrical PFS in men with postprostatectomy incontinence compared with a control intervention. The evidence is insufficient to determine the effects of the technology on health outcomes.

The National Institute for Health and Care Excellence has issued guidance on the management of urinary incontinence of women. While electrical stimulation should not be routinely used to treat women with urinary incontinence it can be considered in women who cannot actively contract pelvic floor muscles to aid motivation and adherence to therapy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have fecal incontinence who receive electrical PFS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Among the RCTs that have evaluated electrical PFS as a treatment for fecal incontinence only one trial was sham-controlled, and it did not find that electrical stimulation improved the net health outcome. Systematic reviews of RCTs have not found that electrical stimulation is superior to control interventions for treating fecal incontinence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have urinary incontinence who receive magnetic PFS, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A systematic review of RCTs on magnetic PFS for urinary incontinence in women concluded that the evidence was insufficient due to the following factors: a low number of trials with short-term follow-up, methodologic limitations, as well as heterogeneity in patient populations, interventions, and outcomes reported. One RCT evaluating magnetic stimulation for treating men with postprostatectomy urinary incontinence reported short-term results favoring magnetic PFS; however, the trial was small and lacked a sham comparator. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have fecal incontinence who receive magnetic PFS, the evidence includes no RCTs or non-RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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EXTRACORPOREAL MAGNETIC INNERVATION (EXMI™) is a technology used to deliver non-invasive electromagnetic stimulation to the muscles of pelvic floor to strengthen and improve neuromuscular control for the treatment of urinary incontinence in women.

PUDENDAL refers to external female genitalia.

INNERVATION is defined as nerve supply to a specific part of the body.

STRESS INCONTINENCE is the involuntary leaking of urine during activities that increase pressure inside the abdomen, such as coughing, sneezing, or jogging.

URGE INCONTINENCE is defined as leakage of urine when there is a strong urge to void.

URGENCY-FREQUENCY is an uncontrollable urge to urinate, resulting in very frequent, small volumes.

URINARY RETENTION is the inability to completely empty the bladder of urine.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of

benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes								
64561	64581	64585	64590	64595	95970	95971	95972	A4290
C1767	C1778	C1787	C1883	C1897	E0740	E0745	E1399	L8679
L8680	L8681	L8682	L8684	L8685	L8686	L8687	L8688	0786T
0787T	0788T	0789T						

ICD-10-CM Diagnosis Codes	Description
N32.81	Overactive bladder
N39.41	Urge incontinence
N39.46	Mixed incontinence
R15.9	Full incontinence of feces
R33.8	Other retention of urine
R33.9	Retention of urine, unspecified
R35.0	Frequency of micturition

R39.14	Feeling of incomplete bladder emptying
R39.15	Urgency of urination

IX. REFERENCES

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Sacral Nerve Neuromodulation /Stimulation

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X. POLICY HISTORY

TOP

MP 6.024	**4/30/2020 Consensus review**. Description/Background, Rationale and Reference updated. Coding reviewed. No change to policy statement.
	4/15/2021 Consensus review. No change to policy statement. References reviewed and updated. Coding reviewed.
	12/14/2022 Consensus review. No change to policy statement. References, policy guidelines and rationale reviewed and updated. FEP statement updated. Coding reviewed.
	5/26/2023 Consensus review. No change to policy statement. References and background updated. Coding reviewed.
	11/29/2023 Admin update. New Codes added effective 1/1/24.