JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Medical Policy Manual** **Medical Policy**	*Policy Number*	CMS21.01
		Effective Date	11/01/2023
		Approval Date	08/15/2023
	Subject **Neuromodulation for Overactive Bladder, Urinary Retention & Fecal Incontinence**	*Supersesedes Date*	11/01/2022
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This document applies to the following Participating Organizations:

EHP	Johns Hopkins Advantage MD	Johns Hopkins Health Plan of Virginia Inc. (JHHPVA)	Priority Partners
US Family Health Plan			

Keywords: Fecal Incontinence, Non-neurogenic Overactive Bladder, Non-obstructive Urinary Retention, OAB, Posterior Tibial Nerve Stimulation, Sacral Nerve Stimulation, Sacral Neuromodulation, Urinary Urgency Incontinence

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I. ACTION

	New Policy	
X	Revising Policy Number	CMS21.01
	Superseding Policy Number	
	Retiring Policy Number	

II. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

III. POLICY

For Advantage MD refer to: Medicare Coverage Database

- National Coverage Determination (NCD) 230.18 for Sacral Nerve Stimulation For Urinary Incontinence

For Employer Health Programs (EHP) refer to:

- Plan specific Summary Plan Descriptions (SPD's)

For Johns Hopkins Health Plan of Virginia Inc. (JHHPVA) refer to: Medicare Coverage Database (Effective 1/1/2024)

- National Coverage Determination (NCD) 230.18 for Sacral Nerve Stimulation for Urinary Incontinence

For Priority Partners refer to: Code of Maryland Regulations

- No specific information located in COMAR 10.67.01 – 10.67.13 (Accessed 06/15/2023

For US Family Health Plan (USFHP) refer to: Tricare Policy Manuals

- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 4, Section 14.1 Urinary System
- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 4, Section 20.1 Nervous System

IV. POLICY CRITERIA

A. Sacral Neuromodulation

1. When benefits are provided under the member's contract, JHHP considers a trial test period of sacral neuromodulation (SNM) (i.e., InterStim™ Continence Control Therapy System, Axonics® Sacral Neuromodulation System) medically necessary for the treatment of overactive bladder (urinary urgency incontinence, and/or urinary urgency-frequency syndrome) when ALL of the following criteria are met:
   a. The member has experienced overactive bladder syndrome, for a duration > 6 months and the condition has resulted in significant disability (e.g., the frequency and/or severity of leakages are limiting the member's ability to work or participate in activities outside the home), AND;
   b. Behavioral treatments (e.g., pelvic floor exercise, biofeedback, timed voids, and fluid management for urinary urgency incontinence or urge-frequency symptoms) have failed, AND;
   c. Pharmacotherapy (e.g., anticholinergics and/or beta-3 agonists for urinary urgency incontinence or urge-frequency symptoms, and/or antibiotics for urinary infection if present) have failed or are medically contraindicated, AND;
   d. Absence of a severe or rapidly progressive neurological disease.
2. When benefits are provided under the member's contract, JHHP considers permanent implantation of a sacral neuromodulation device (i.e., Axonics® Sacral Neuromodulation System, InterStim™ X, InterStim™ II, InterStim™ Micro) medically necessary for the treatment of overactive bladder (urinary urgency incontinence, and/or urinary urgency-frequency syndrome) when ALL of the following criteria are met:
   a. ALL of the criteria (a) through (d) above are met, AND;
   b. The trial test period of SNM provided at least a 50% decrease in frequency and/or urinary urgency incontinence symptoms
3. When benefits are provided under the member's contract, JHHP considers a trial test period of SNM medically necessary for the treatment of non-obstructive urinary retention when ALL of the following criteria are met:
   a. The member has experienced non-obstructive urinary retention for a duration > 6 months and the condition has resulted in significant disability (e.g., the need to catheterize and/or the inability to empty the bladder are limiting the member's ability to work or participate in activities outside the home), AND;
   b. Behavioral treatments (e.g., pelvic floor relaxation exercise, timed voids, and fluid management) or other therapies (self-catheterization for retention patients) have failed, AND;

c. Pharmacotherapy (e.g., alpha blockers for functional outflow obstruction and/or urinary retention, and/or antibiotics for urinary infection if present) have failed, AND;
d. Absence of a severe or rapidly progressive neurological disease.

4. When benefits are provided under the member's contract, JHHP considers permanent implantation of a sacral neuromodulation device (i.e., Axonics® Sacral Neuromodulation System, InterStim™ X, InterStim™ II, InterStim™ Micro) medically necessary for the treatment of non-obstructive urinary retention when ALL of the following criteria are met:
   a. All of the criteria (a) through (d) above are met, AND;
   b. The trial test period of SNM provided at least a 50% decrease in the need for intermittent catheterization.
5. When benefits are provided under the member's contract, JHHP considers a trial test period of SNM medically necessary for the treatment of fecal incontinence when ALL of the following criteria are met:
   a. The member has experienced fecal incontinence for a duration > 6 months and the condition has resulted in significant disability (e.g., the frequency and/or severity of fecal leakage are limiting the member's ability to work or participate in activities outside the home), AND;
   b. Behavioral treatments (e.g., pelvic floor exercise, biofeedback, dietary modification) or other therapies have failed, AND;
   c. Pharmacotherapy (e.g., stool bulking agents) have failed, AND;
   d. Condition is not related to an anorectal malformation or chronic inflammatory bowel disease, AND;
   e. 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, AND;
   f. Fecal incontinence is not related to a neurological condition, including but not limited to peripheral neuropathy or spinal cord injury.
6. When benefits are provided under the member's contract, JHHP considers permanent implantation of a sacral neuromodulation device (i.e., Axonics® Sacral Neuromodulation System, InterStim™ X, InterStim™ II, InterStim™ Micro) medically necessary for the treatment of fecal incontinence when ALL of the following criteria are met:
   a. All of the criteria (a) through (f) above are met, AND;
   b. The trial test period of SNM provided at least a 50% decrease in fecal incontinence.
7. Unless specific benefits are provided under the member's contract, JHHP considers the use of sacral neuromodulation experimental and investigational for all other conditions, as it does not meet Technology Evaluation Criteria (TEC). Refer to: CMS01.00 Medical Policy Introduction

B. Posterior Tibial Nerve Stimulation
   1. Percutaneous Tibial Nerve Stimulation
      a. When benefits are provided under the member's contract, JHHP considers a standard treatment regimen of 30-minute weekly sessions for 12 weeks of percutaneous tibial nerve stimulation (i.e., Urgent PC® system, Medtronic NURO™ system) medically necessary for the treatment of overactive bladder (urinary urgency incontinence, and/or urinary urgency-frequency syndrome) when ALL of the following criteria are met:
         i. The member has experienced overactive bladder syndrome for a duration > 6 months and the condition has resulted in significant disability (e.g., the frequency and/or severity of leakages are limiting the member's ability to participate in activities outside the home), AND;
         ii. Behavioral treatments (e.g., pelvic floor exercise, biofeedback, timed voids, and fluid management for urinary urgency incontinence or urge-frequency symptoms) have failed, AND;

iii. Pharmacotherapy (e.g., anticholinergics and/or beta-3 agonists for urinary urgency incontinence or urge-frequency symptoms, and/or antibiotics for urinary infection if present) have failed or are medically contraindicated.

b. Maintenance therapy of a 30-minute monthly session of percutaneous tibial nerve stimulation is considered medically necessary for the treatment of overactive bladder if ALL of the following criteria are met:
   i. The member has completed the initial standard treatment regimen of 30-minute weekly sessions for 12 weeks of percutaneous tibial nerve stimulation, AND;
   ii. The initial 12 weeks of treatment resulted in at least a 50% decrease in frequency and/or urinary urgency incontinence symptoms.

c. Unless specific benefits are provided under the member's contract, JHHP considers the use of percutaneous tibial nerve stimulation experimental and investigational for all other conditions, as it does not meet Technology Evaluation Criteria (TEC). Refer to: CMS01.00 Medical Policy Introduction

2. Transcutaneous Tibial Nerve Stimulation
   a. Unless specific benefits are provided under the member's contract, JHHP considers the use of transcutaneous tibial nerve stimulation for the treatment of overactive bladder (urinary urgency incontinence, and/or urinary urgency-frequency syndrome) and fecal incontinence experimental and investigational as it does not meet Technology Evaluation Criteria (TEC). Refer to: CMS01.00 Medical Policy Introduction
3. Implantable Tibial Nerve Stimulator
   a. Unless specific benefits are provided under the member's contract, JHHP considers the use of a permanent implantable tibial nerve stimulator device (i.e., Bluewind RENOVA™, ECoin™, Stimguard®) for the treatment of overactive bladder (urinary urgency incontinence, and/or urinary urgency-frequency syndrome) and fecal incontinence experimental and investigational as it does not meet Technology Evaluation Criteria (TEC). Refer to:CMS01.00 Medical Policy Introduction

V. DEFINITIONS

Overactive Bladder Syndrome: (or OAB Urgency) is 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 (Haylen, 2010).

Posterior Tibial Nerve Stimulation (PTNS): The stimulation of the posterior tibial nerve to deliver retrograde neuromodulation to the sacral nerve plexus which controls bladder function. There are 3 methods to achieve PTNS:

- Percutaneous Tibial Nerve Stimulation via insertion of a needle electrode
- Transcutaneous Tibial Nerve Stimulation via placement of surface electrode pads
- Implantable Tibial Nerve Stimulation Device via surgical implantation of the device (Bhide et al., 2020)

Sacral Neuromodulation: (or Sacral Nerve Stimulation) is the application of a mild electrical pulse to the sacral nerves through a surgically implanted neuromodulation system. The electrical pulses modulate the sacral nerves that influence the functioning of the bladder, bowel, urinary, and anal sphincters, and the pelvic floor muscles (Hayes, 2013).

Urgency Urinary Incontinence: The involuntary leakage of urine, associated with a sudden compelling desire to void (AUA, 2019).

VI. BACKGROUND

Sacral nerve stimulation (SNS) or sacral neuromodulation (SNM) is a procedure often used in patients with severe bladder and bowel issues. If conservative treatment options such as diet modifications, behavioral therapies, and certain medications prove to be ineffective, the patient is then recommended for sacral neuromodulation. The procedure targets nerves that control the bladder and bowel and involves a neurotransmitter device which electrically stimulates nerves in these areas. The procedure is performed in two stages: the first, a trial phase involves electrode placement to determine if symptoms are improved sufficiently in order to proceed to the second stage, implantation of a pulse generator (American Urogynecology Society, 2018). The American Urological Association (AUA) guideline, Diagnosis and Treatment of Non-Neurogenic Overactive Bladder (OAB) in Adults, recommends sacral neuromodulation (SNS) as third-line treatment in a carefully selected patient population characterized by severe refractory OAB symptoms or patients who are not candidates for second-line therapy and are willing to undergo a surgical procedure (AUA, 2019).

There are several sacral neuromodulation devices available, including the InterStim™ Micro system, InterStim™ II, InterStim™ X (Medtronic), and Axonics® System (Axonics), which include MRI- compatible options. The InterStim™ Micro and Axonics® have rechargeable implanted programmable device options, which can increase battery life to 15 years or more. These devices require the patients to have the cognitive ability and inclination to control the technology, perform a testing procedure, keep track of the impact of stimulation on urinary or bowel incontinence episodes, urgency, and pad usage for a week or two, and manage the recharging process. The InterStimII device has a non-rechargeable battery that requires replacement every three to five years (Lukacz, 2023).

Another neuromodulation technique for treatment of OAB and urge urinary incontinence is posterior tibial nerve stimulation (PTNS). In this approach, stimulation of the posterior tibial nerve delivers retrograde neuromodulation to the sacral nerve plexus which controls bladder function. PTNS can be achieved via percutaneous needle electrode, transcutaneous surface electrodes, or the novel wireless implantable tibial nerve stimulator (Bhide, et al., 2020). Per AUA guidelines, "clinicians may offer posterior tibial nerve stimulation (PTNS) as third-line treatment in a carefully selected patient population" (AUA, 2019). The National Institute for Health and Care Excellence (NICE) concurs with the AUA in their management guidelines for urinary incontinence in women, which recommends offering percutaneous sacral nerve stimulation to women for treatment of OAB that has not responded to conservative management (NICE, 2019).

There is ongoing research examining wireless implantable devices for posterior tibial nerve stimulation (i.e., BlueWind Renova™, StimGuard ®, ECoin™, Bioness StimRouter™) and transcutaneous tibial nerve stimulation via surface electrode pads for the treatment of OAB. Additional research studies and ongoing trials are needed to further evaluate the safety and long-term efficacy of these methods (Vollstedt & Gilleran, 2020). The current NICE guidelines for management of urinary incontinence in women recommends not to offer transcutaneous tibial nerve stimulation for treatment of OAB (NICE, 2019).

VII. CODING DISCLAIMER

Note: The following CPT/HCPCS codes are included below for informational purposes and may not be all inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document

and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

Note: All inpatient admissions require preauthorization.

Adherence to the provision in this policy may be monitored and addressed through post-payment data analysis and/or medical review audits
Advantage MD: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Employer Health Programs (EHP): Specific Summary Plan Descriptions (SPDs) supersedes JHHP Medical Policy. If there are no criteria in the SPD, apply the Medical Policy criteria.
Johns Hopkins Health Plan of Virginia Inc. (JHHPVA): Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.
US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

VIII. CODING INFORMATION

	CPT® CODES ARE FOR INFORMATIONAL PURPOSES
CPT® CODES	**DESCRIPTION**
64561	Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
64581	Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming

95971	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral(i.e., peripheral nerve, sacral nerve, (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour.

	HCPCS CODES ARE FOR INFORMATIONAL PURPOSES
HCPCS CODES	**DESCRIPTION**
A4290	Sacral nerve stimulation test lead, each
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1883	Adapter/extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

	ICD-10 CODES ARE FOR INFORMATIONAL PURPOSES
ICD10 CODES	**DESCRIPTION**
N31.8	Other neuromuscular dysfunction of bladder
N32.81	Overactive bladder
N39.41	Urge incontinence
N39.46	Mixed incontinence
R15.9	Full incontinence of feces
R32	Unspecified urinary incontinence
R33.8	Other retention of urine
R33.9	Retention of urine, unspecified
R35.0	Frequency of micturition
R39.11	Hesitancy of micturition
R39.14	Feeling of incomplete bladder emptying
R39.15	Urgency of urination

IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

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XI. APPROVALS

Historical Effective Dates: 08/20/2002, 10/22/2003, 10/22/2004, 10/21/2005, 10/19/2006, 06/25/2008, 06/04/2009, 04/02/2010, 08/23/2011, 09/06/2013, 12/04/2015, 12/01/2017, 02/03/2020, 11/01/2021, 11/1/2022, 11/01/2023