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Medical Policy

Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure) for Incontinence and Urinary Conditions

Policy Number: OCA 3.563
Version Number: 20
Version Effective Date: 01/01/22

Product Applicability	☒ **All Plan+ Products**
WellSense Health Plan ☒ NH Medicaid ☒ NH Medicare Advantage	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ MassHealth MCO ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☒ Senior Care Options

+ Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan considers implantable sacral nerve stimulation (SNS), also known as sacral neuromodulation, to be **medically necessary** when used for the treatment of chronic urinary incontinence, urgency-frequency syndrome, non-obstructive urinary retention, or chronic fecal incontinence and when applicable medical criteria are met; this includes peripheral nerve stimulation test and tined lead procedure before the implantation of the permanent SNS device. SNS (including peripheral nerve stimulation testing and tined lead procedure) for the treatment of other conditions and/or the use of a wireless sacral nerve stimulator (e.g., StimGuard wireless SNS and StimWave Freedom Spinal Cord Stimulation System by Medtronic, Inc.) is considered **experimental and investigational or NOT medically necessary** by the Plan until the clinical utility and clinical validity of the device can be consistently established; a wireless SNS uses a small external transmitter and microsize

neurostimulator that is injected into the targeted nerve location through the lumen to treat an overactive bladder. Plan prior authorization is required.

Clinical Criteria

Sacral nerve stimulation (SNS) initial testing or permanent **implantation** of a SNS device (e.g., InterStim™ system by Medtronic, Inc.) is considered medically necessary when applicable Plan criteria are met in EITHER item A or item B:

A. **Sacral Nerve Stimulation (SNS) to Treat Urinary Conditions:**

Applicable criteria must be met based on the phase of treatment in EITHER item 1 (Initial Testing Phase) or item 2 (Permanent Implantation):

1 **Initial Testing Phase for Implanted SNS:**

Trial period of implantable SNS (with either peripheral nerve stimulation or a temporarily implanted lead with stage one of the tined lead procedure) is considered medically necessary when ALL criteria are met in items a through f:

a. Member is experiencing at least ONE (1) of the **urinary symptoms** in items (1) through (3) **for at least 6 months**:

(1) Non-obstructive urinary retention; OR

(2) Urgency-frequency syndrome; OR

(3) Urinary urge incontinence; AND

b. Member's urinary symptoms are NOT related to a neurologic condition; AND

c. Member's conservative treatment meets ONE (1) of the criteria in item (1) or item (2):

(1) Member is medically refractory to conservative therapy and has failed 6 months of behavioral therapy and 3 months of pharmacological therapy (which included a trial of at least 2 anti-cholinergic agents or a trial of 1 anti cholinergic agent and 1 beta 3 adrenergic receptor agonist); OR

(2) Member cannot tolerate a minimum of 6 consecutive months of conservative treatment due to a significant disability (e.g., frequency or severity impacts ability to work or participate in activities outside of the home); AND

d. Member is 18 years of age or older on the date of service; AND

e. Member is willing to comply with the treatment protocol and has the cognitive capacity to use the remote control to optimize device function during the testing and treatment phases; AND

f. Member's current treatment plan does NOT include the use of percutaneous tibial nerve stimulation (PTNS) for non-neurogenic urinary overactive bladder symptoms; OR

2. **Permanent Implantation of SNS:**

Permanent implantation of a SNS device is considered medically necessary when BOTH criteria are met in item a and item b:

a. Member meets all the criteria listed above for the peripheral nerve stimulation test or stage one of the tined lead procedure (to estimate potential response to SNS); AND

b. Member has experienced a **50% or greater relief of incontinence or primary symptoms for at least 48 hours** during the percutaneous trial or stage one of the tined lead test as measured by voiding diaries; OR

B. **Sacral Nerve Stimulation (SNS) to Treat Chronic Fecal Incontinence:**

Applicable criteria must be met based on the phase of treatment in EITHER item 1 (Initial Testing Phase) or item 2 (Permanent Implantation):

1. **Initial Testing Phase of Implanted SNS:**

Trial period of implantable SNS (with either peripheral nerve stimulation or a temporarily implanted lead with stage one of the tined lead procedure) is considered medically necessary to treat fecal incontinence after review and approval of a Plan Medical Director and when ALL criteria are met in items a through f:

a. Member has chronic fecal incontinence with greater than 2 incontinent episodes on average per week for at least 6 months in duration or for at least 12 months after vaginal childbirth; AND

b. Member's fecal incontinence is NOT related to a neurologic condition; AND

c. Member's conservative treatment (before the request for the initial testing phase of implanted sacral nerve stimulation) meets ONE (1) of the criteria in item (1) or item (2):

(1) Member is medically refractory to conservative therapy and BOTH criteria are met in item (a) and item (b):

(a) Failure of behavioral therapy (e.g., dietary modification, pelvic floor retraining); AND

(b) Failure of pharmacological therapy; AND

(2) Member cannot tolerate conservative treatment due to a significant disability (e.g., frequency or severity impacts ability to work or participate in activities outside of the home); AND

d. If the member has medical history of chronic inflammatory bowel disease (IBD), IBD does NOT involve the anorectum; AND

e. Member is 18 years of age or older on the date of service; AND

f. Member is willing to comply with the treatment protocol and has the cognitive capacity to use the remote control to optimize device function during the testing and treatment phases; OR

2. **Permanent Implantation of SNS:**

Permanent implantation of a SNS device for the treatment of fecal incontinence is considered medically necessary after review and **approval of a Plan Medical Director** and when ALL criteria are met in items a through c:

a. Member meets all the criteria above for the peripheral nerve stimulation test or stage one of the tined lead procedure (to estimate potential response to SNS); AND

b. Member has experienced a **50% or greater relief of incontinence symptoms for at least 48 hours** during the percutaneous trial or stage one of the tined lead test as measured by elimination journals.

Limitations and Exclusions

1. **Contraindications for Sacral Nerve Stimulation (SNS):**

The use of implantable SNS (including associated testing) is contraindicated in a member when at least ONE (1) of the criteria is met in items a through e:

a. Member has chronic inflammatory bowel disease involving the anorectum, mechanical obstruction, or malformation in the applicable anatomical area (e.g., benign prostatic hypertrophy, cancer, urethral stricture, congenital anorectal malformation, defects of the

external anal sphincter over 60 degrees, visible sequelae of pelvic radiation, active anal abscesses, fistulae); OR

b. Member is receiving any form of diathermy or is expected to receive diathermy during the duration of treatment with sacral nerve stimulation; OR

c. Member has a pacemaker or implantable defibrillator; OR

d. Member is pregnant or plans to become pregnant during the duration of treatment with sacral nerve stimulation; OR

e. Member who has had rectal surgery in the previous 12 months, or in the case of cancer, the patient has had rectal surgery in the past 24 months.

2. **Indications for SNS Considered Experimental and Investigational or NOT Medically Necessary:**

The Plan considers ANY uses of SNS (including associated testing) listed in items a through f to be experimental and investigational or NOT medically necessary due to limited evidence demonstrating the clinical utility and clinical validity of SNS for these indications or conditions:

a. SNS used for the treatment of chronic constipation, chronic pelvic pain, stress incontinence, and/or another indication not specified in the Clinical Criteria section.

b. SNS used for a member age 15 or younger on the date of service and/or a diabetic member. Plan Medical Director review is required for members age 16 or 17, as stated below.

c. Member's symptoms are related to a neurological disease (e.g., multiple sclerosis, neurogenic detrusor over activity, peripheral neuropathy, or spinal cord injury).

d. Member is unwilling or unable to comply with the treatment protocol and/or does not have the cognitive capacity to use the remote control to optimize device function during the testing and treatment phases.

e. The use of a wireless sacral nerve stimulator (e.g., StimGuard) because the safety and efficacy of the wireless devices have not been adequately studied.

f. The use of posterior tibial nerve stimulation, including percutaneous tibial nerve stimulation (PTNS) and/or transcutaneous posterior tibial nerve stimulation (TPTNS) with a member who has an implantable SNS device or has initiated the initial testing phase of an implantable SNS. Posterior tibial nerve stimulation may NOT be administered concurrently with SNS. Review the Plan's *Posterior Tibial Nerve Stimulation (Percutaneous or Transcutaneous)* medical policy, policy number OCA 3.562 for applicable medical necessity criteria for these services.

3. **Plan Medical Director Review Required:**

   Plan Medical Director review is required for ANY type of requests listed in item a or item b:

   a. Plan Medical Director review is required for the use of an implantable sacral nerve stimulation (SNS) for members age 16 or 17 on the date of service, including the initial testing phase and/or permanent implantation. The use of implantable SNS (including associated testing) is considered experimental and investigational when used for a member age 15 or younger on the date of service.

   b. **All requests for implantable SNS** (including initial testing phase and/or permanent implantation) to **treat fecal incontinence require Plan Medical Director review** and approval. In addition, ALL applicable criteria in item B of the Clinical Criteria section (Sacral Nerve Stimulation to Treat Chronic Fecal Incontinence) must be met and documented in the member's medical record. While clinical studies have demonstrated the clinical efficacy of implantable SNS for the treatment of fecal incontinence, adverse events are common and reoperation rates are estimated at 20%.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and WellSense Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, NCD 23.18 includes medical necessity criteria for the use of sacral nerve stimulation (SNS) for the treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

Applicable Coding

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United Stated by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Since the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior

notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in this Applicable Coding section. Review the Plan's reimbursement policies for Plan billing guidelines. Coverage for services is subject to benefit eligibility under the member's benefit plan in effect at the time of the service. Member benefit documents are available at the following websites: www.bmchp.org for BMC HealthNet Plan members, www.SeniorsGetMore.org for Senior Care Options members, www.wellsense.org for WellSense New Hampshire Medicaid members, and www.WellSense.org/Medicare for WellSense Medicare Advantage HMO members.

CPT Codes	Description: Codes Covered When Medically Necessary
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed Plan note: Percutaneous trial/temporary stimulation to estimate potential response to SNS.
64581	Open implantation of neurostimulator electrode array; 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

HCPCS Codes	Description: Codes Covered When Medically Necessary
A4290	Sacral nerve stimulation test lead, each
E0745	Neuromuscular stimulator, electronic shock unit
L8680	Implantable neurostimulator electrode, each Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
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 Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension Plan note: Code is NOT payable for the Senior Care Options and WellSense Medicare Advantage HMO products.
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only

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Policy History

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A Internal Approval: 10/03/06	12/03/06 Version 1	Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)	Quality and Clinical Management Committee (Q&CMC)

*Effective Date for the BMC HealthNet Plan Commercial Product: 01/01/12
*Effective Date for the WellSense New Hampshire Medicaid Product: 01/01/13
*Effective Date for the Senior Care Options Product: 01/01/16
*Effective Date for the WellSense Medicare Advantage HMO Product: 01/01/22

Note: Effective 05/01/13, this policy replaced *Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence* policy, policy number OCA 3.56, to include the medical necessity criteria for implantable sacral nerve stimulation and the policy title was changed to *Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure) for Incontinence and Urinary Conditions.*

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date and Version Number**	**Approved by**
09/11/07	Updated template and added coding.	Version 2	09/11/07: MPCTAC 09/25/07: Utilization Management Committee (UMC) 10/15/07: Quality Improvement Committee (QIC)
09/09/08	No changes.	Version 3	09/09/08: MPCTAC 09/30/08: UMC 10/22/08: QIC
09/22/09	Updated references. No changes to criteria.	Version 4	09/22/09: MPCTAC 10/28/09: QIC
09/01/10	Updated template and references. No changes to criteria.	Version 5	10/20/10: MPCTAC 11/22/10: QIC
10/01/11	Updated limitations to include that sacral nerve stimulation for the treatment of fecal incontinence and posterior tibial nerve stimulation for the treatment of symptoms associated with overactive bladder are considered experimental and investigational. Updated references and coding.	Version 6	10/19/11: MPCTAC 11/29/11: QIC
07/20/12	Off cycle review for Well Sense Health Plan: Updated title, revised Summary statement, added posterior tibial stimulation to Description of Item or Service, reformatted Medical Policy Statement, updated Definitions, revised language in Applicable Coding section, updated code list.	Version 7	08/13/12: MPCTAC 09/13/12: QIC
12/01/12	Review for effective date 05/0/13. Separated pelvic floor electrical stimulation, implantable sacral nerve stimulation, and posterior tibial nerve stimulation into three separate policies; policy formerly titled *Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence* (formerly OCA: 3.65). Revised title and re-numbered policy. Updated language in Summary, Description of Item or Service,	05/01/13 Version 8	12/19/12: MPCTAC 01/31/13: QIC

Policy Revisions History			
	Definitions, Applicable Coding, and Clinical Background Information sections. Reformatted criteria in Medical Policy Statement section and added criteria for peripheral nerve stimulation test and two-stage tined lead procedure, updated references, and added limitations. Revised applicable code list. Referenced the following policies: *Experimental and Investigational Treatment*, *Non-Implantable Pelvic Floor Electrical Stimulation for Urinary Incontinence, Posterior Tibial Nerve Stimulation,* and *Biofeedback for Urinary Incontinence.* Changed name of policy category from "Clinical Coverage Guidelines" to "Medical Policy."		
12/01/13:	Review for effective date 02/01/14. Revised Description of Item or Service section. Reformatted Medical Policy Statement section without changing criteria. Updated code definitions without changing applicable code list. Updated references.	02/01/14 Version 9	12/18/13: MPCTAC 01/21/14: QIC
12/01/14	Review for effective date 02/01/15. Updated references.	02/01/15 Version 10	12/17/14: MPCTAC 01/14/15: QIC
10/01/15	Review for effective date 12/01/15. Updated template with list of applicable products and corresponding notes.	12/01/15 Version 11	10/21/15: MPCTAC 11/11/15: QIC
10/21/15	Review for effective date 02/01/16. Revised limitations. Updated References, Definitions, and Clinical Background Information sections.	02/01/16 Version 12	10/21/15: MPCTAC 11/11/15: QIC
11/25/15	Review for effective date 02/01/16. Revised language in the Applicable Coding section.	02/01/16 Version 13	11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
10/01/16	Review for effective date 12/01/16. Administrative changes made to the Summary, Medical Policy Statement, Definitions, Clinical Background Information, References, and References to Applicable Laws and Regulations sections. No change to criteria or applicable code list.	12/01/16 Version 14	10/19/16: MPCTAC 11/09/16: QIC

Policy Revisions History			
10/01/17	Review for effective date 01/01/18. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Other Applicable Policies sections. Criteria revised in the Medical Policy Statement and Limitations sections.	01/01/18 Version 15	10/24/17: MPCTAC (electronic vote)
10/01/18	Review for effective date 01/01/19. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Other Applicable Policies sections. Revised criteria in the Medical Policy Statement and Limitations sections.	01/01/19 Version 16	10/17/18: MPCTAC
09/01/19	Review for effective date 10/01/19. Administrative changes made to the Clinical Background Information, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Revised Plan notes in the Applicable Coding section.	10/01/19 Version 17	09/18/19: MPCTAC
09/01/20	Review for effective date 10/01/20. Administrative changes made to the References and Other Applicable Policies sections.	10/01/20 Version 18	09/16/20: MPCTAC
10/01/21	Review for effective date 01/01/22. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria section, and Limitations section renamed Limitations and Exclusions section. Added WellSense Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Limitations and Exclusions, Applicable Coding, and References sections. Criteria revised in the Clinical Criteria section.	01/01/22 Version 19 Not implemented - replaced with Version 20	10/20/21: MPCTAC
12/01/21	Review for effective date 01/01/22. Industry-wide code description change in the Applicable Coding section. Revisions approved in version 19 implemented.	01/01/22 Version 20	Not applicable because industry-wide code description change; 12/15/21: MPCTAC

Policy Revisions History			
			review

Next Review Date

09/01/22

Authorizing Entity

MPCTAC

Disclaimer Information: +

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.