Clinical Policy: Urinary Incontinence Devices and Treatments

Reference Number: WNC.CP.126 Coding Implications
Last Review Date: 02/2025 Revision Log

See Important Reminder **at the end of this policy for important regulatory and legal information.**

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description

Sacral neuromodulation (SNM) or sacral nerve stimulation (SNS) refers to stimulation of nerves that innervate the bladder and pelvic floor to treat lower urinary tract dysfunction. SNS involves both a temporary test stimulation to determine if an implantable stimulator would be effective, and a permanent implantation in appropriate candidates.

Urethral bulking agents (UBAs) are injectable substances used to increase tissue bulk, which can be injected periurethrally to treat urinary incontinence. The U.S. Food and Drug Administration (FDA) has approved several bulking agent products for treating urinary incontinence.[1,2]

Policy/Criteria

I. It is the policy of WellCare of North Carolina® that a *trial* of Sacral neuromodulation (SNM) with a United States Food and Drug Administration (FDA) approved device is **medically necessary** to treat lower urinary tract dysfunction when **all** of the following criteria are met:

- **A.** Diagnosis is non-obstructive urinary retention or overactive bladder.
- **B.** Symptoms of incontinence, urgency/frequency, or urinary retention have been present for at least **six** months and have resulted in significant disability, such as the limited ability to work or participate in activities outside of the home;
- **C.** Failure of conservative measures, **one** of the following:
  1. For urgency/frequency or incontinence, bladder training, pelvic floor physical therapy with biofeedback, and pharmacologic treatment;
  2. For non-obstructive urinary retention, pharmacologic treatments **or** intermittent self-catheterization, unless not well-tolerated.

II. It is the policy of WellCare of North Carolina® that *permanent placement* of SNM, with a United States FDA approved device, is medically necessary to treat lower urinary tract dysfunction when **both** of the following criteria are met:

- **A.** Criteria in section I are met;
- **B.** A percutaneous stimulation test has provided **at least** a 50% reduction in incontinence, retention, or urgency/frequency symptoms prior to permanent device implantation.

III. It is the policy of WellCare of North Carolina® that injection of United States Food and Drug Administration (FDA) approved urethral bulking agents (UBA) is **medically necessary** when **all** of the following criteria are met:

- **A.** Diagnosis of persistent or recurrent stress urinary incontinence due to one of the following:
  1. Intrinsic sphincter deficiency;
  2. Post-bladder support surgery;
  3. Post- traumatic or surgical injury;
- **B.** Failure of conservative management such as pelvic floor therapy, biofeedback, electrical stimulation, **or** pharmacotherapies;
- **C.** Member is unable to tolerate surgery or does not wish to have surgery.

*A recurrence of incontinence following a successful treatment series (i.e., 6-12 months previously), may benefit from additional treatments. [7]

IV. It is the policy of WellCare of North Carolina® that there is insufficient evidence in the published peer-reviewed literature to support the use of UBA injection of autologous fat, non- FDA approved procedures, and any other circumstances than those specified above.

Background

The three major categories of treatment for urinary incontinence are behavioral, pharmacologic and surgical. The first choice should be the least invasive treatment with the fewest potential adverse complications for the patient. Before treatment begins, a complete evaluation and appropriate urodynamic testing should be completed.

Sacral neuromodulation (SNM)

SNM, a minimally invasive form of electrical stimulation, is delivered via the InterStim system. This implantable system involves chronic modulation of the S3 and, less frequently, the S4 nerve via a transforaminal route. A wire lead in the foramen is connected to a stimulation device. Modulation implies that the therapy is thought to act indirectly, via a central afferent mechanism, targeting reflex centers in the spinal cord and pons, influencing reflexes between the bladder, urethral sphincter, and pelvic floor. Stimulation implies a more direct effect on efferent nerves, as in functional electrical stimulation.

A distinct advantage of SNM is that it is tested for potential success prior to surgical implantation of a permanent device. The evaluation gives patients and physicians an opportunity to find out in as few as 3 to 7 days whether adequate symptom reduction is achieved. The most common adverse events experienced during clinical studies of patients with SNM included pain at implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations. Any of these may require additional surgery or cause return of symptoms.

In the United States, SNM is approved for the treatment of nonobstructive urinary retention. Success rates in general are not as promising as for urgent urinary incontinence and overactive bladder, but it is reasonable to try prior to more invasive and permanent solutions. [1]

A prospective study has demonstrated that sacral nerve stimulation for refractory urinary urge incontinence had a positive benefit of 30.8 months.[4] A meta-analysis noted that sacral neuromodulation is an effective therapy for the treatment of nonobstructive urinary retention.[5] A prospective, randomized, multicenter trial demonstrated that SNM has shown to be a safe and effective treatment for overactive bladder (OAB) patients with mild to moderate symptoms. In studies comparing patients who received SNM with patients who delayed implantation and continued standard management, those with SNM experienced significant improvements in quality of life.[6,7]

American Urologic Association *(AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU)*
AUA/SUFU recommendations state that clinicians may offer SNM as third-line treatment in a carefully selected patients who have severe refractory OAB symptoms or patients who are not candidates for second line therapy and are willing to undergo a surgical procedure. Recommendation (Grade C; benefits outweigh risk/burdens).[3]

National Institute for Health and Care Excellence (NICE)
According to NICE, sacral nerve stimulation (SNS) can be recommended for those with urge incontinence and urgency-frequency when the patient understands what is involved and agrees to the treatment. SNS should only be tried when other treatments for incontinence have been unsuccessful, changes in daily lives have been made, or learning techniques to help control the bladder, have been put in place. [8]

Periurethral Bulking Agents
Urethral bulking agent (UBA) therapy, also known as periurethral injection therapy, is rarely used as a primary treatment for stress urge incontinence (SUI) but remains an option for women with persistent/recurrent SUI who wish to avoid surgery or who are unable to tolerate surgical procedure.[9] Although UBA is an option for this type of incontinence, it can be more invasive and usually requires repeat injections. The most common complications associated with UBA are urinary retention and urinary tract infection, but these are easily managed.[3,10,11,12]

Candidates for periurethral bulking agents also include women with intrinsic sphincter deficiency and men who are incontinent after prostate surgery. UBA used to treat intrinsic sphincteric deficiency is being performed less frequently in current practice. Surgical interventions are generally more efficacious in both, whereas injectable therapy can be considered in cases in which surgery is contraindicated or as an adjunct to surgery if symptoms persist. In women with severe intrinsic sphincter deficiency or urethral hypermobility, the best long-term results are obtained with a pubovaginal sling or retropubic bladder neck suspension procedure.[3,10,11,12]

United States Food and Drug Administration (FDA) approved products for periurethral injection therapy include[20,21,22,23]:

- Carbon-coated zirconium oxide beads suspended in a water-based gel (Durasphere EXP, FDA approved 1999)

- Crosslinked polydimethylsiloxane (Macroplastique, FDA approved October 30, 2006)
- Calcium hydroxylapatite suspended in a water and glycerin gel (Coaptite, FDA Approved November 10, 2005)
- Polyacrylamide hydrogel (Bulkamid): a homogeneous, stable hydrophilic polymer gel (FDA approved January 28, 2020)

Evidence in major reviews shows low efficacy rates compared with surgical incontinence therapies, a need for repeat treatments because of symptom recurrence, and problems with the injection of some synthetic agents.[9]

Currently, there has been increased interest in autologous skeletal muscle derived stem cell injections for the treatment of SUI specifically due to intrinsic urinary incontinence. This therapy involves obtaining a biopsy of the patient's skeletal muscle, which is then processed ex vivo to ensure a large quantity of myogenic cells in the product. The product is then injected into the urethral sphincter, transurethrally or periurethrally. Additional peer-reviewed studies are necessary to confirm the efficacy of this treatment. [10]

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2025, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description
51715	Endoscopic injection of implant material into the submucosal tissue of the urethra and/or bladder neck
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Incision for 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
A4290	Sacral nerve stimulation test lead, each

HCPCS ®* Codes	Description
L8603	Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies
L8606	Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies
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
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
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original approval date	03/21	06/21
Added HCPCS code A4290. Reviewed CPT and ICD-10-CM codes. References reviewed, updated and reformatted.	01/22	02/22
Annual review. Replaced investigational language in IV, to "insufficient evidence in the published peer-reviewed literature to support the use of UBA injection of autologous fat, non- FDA approved procedures, and any other circumstances than those specified above." In Background added, "surgical implantation of a permanent device." and "• Polyacrylamide hydrogel (Bulkamid): a homogeneous, stable hydrophilic polymer gel (FDA approved 1/28/2020)" References reviewed, updated and reformatted.	11/22	11/22
Updated criteria section to clarify abbreviations. Criteria I.C.1 updated to include continence-support pessaries as a conservative measure. Updated background with no impact on criteria. Removed ICD-10 codes. References reviewed and updated.	12/22	12/22

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
NCHC verbiage removed from NC Guidance Verbiage.	04/23	04/23
Annual Review. Removed continence support pessaries from criteria I.C.1.	08/23	08/23
Annual Review. Minor rewording in Criteria with no clinical significance. Background updated with no impact on criteria. References reviewed and updated.	08/24	08/24
Annual review. Added language to Criteria I. and Criteria II. regarding a United Sates Food and Drug Administration (FDA) approved device. Criteria II.B. updated verbiage to state "at least" a 50% reduction in incontinence. Criteria III.B. reworded for flow and changed Kegel exercises to pelvic floor therapy. Criteria III.C. changed "patient" to "Member." References reviewed and updated.	02/25	02/25

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North Carolina Guidance

Eligibility Requirements

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health

in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:

NCTracks Provider Claims and Billing Assistance Guide:
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
EPSDT provider page: https://medicaid.ncdhhs.gov/

Provider(s) Eligible to Bill for the Procedure, Product, or Service
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance
Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information
Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

a. Claim Type - as applicable to the service provided:
   Professional (CMS-1500/837P transaction)
   Institutional (UB-04/837I transaction)
   Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of

specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.
   Unlisted Procedure or Service
   CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.
   HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service
d. Modifiers - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
   For Medicaid refer to Medicaid State Plan:
   https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.