Clinical Policy: Urinary Incontinence Devices and Treatments

Reference Number: CP.MP.142 Coding Implications
Date of Last Revision: 11/25 Revision Log

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

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]

Note:

- *For biofeedback treatment for urinary incontinence, please refer to CP.MP.168 Biofeedback.*
- *For posterior tibial nerve stimulation treatment for urinary incontinence, please refer to CP.MP.133 Posterior Tibial Nerve Stimulation for Voiding Dysfunction.*

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® 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. Symptoms are not related to a neurologic condition;
   D. 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, intermittent self-catheterization, unless not well-tolerated, and pharmacologic treatment.

II. It is the policy of health plans affiliated with Centene Corporation 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 provided at least a 50% reduction in incontinence, retention, or urgency/frequency symptoms prior to permanent device implantation.

III. It is the policy of health plans affiliated with Centene Corporation that injection of United States 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, and pharmacotherapies;
C. Member/enrollee is unable to tolerate surgery or does not wish to have surgery.

IV. It is the policy of health plans affiliated with Centene Corporation 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 three to seven 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 urgency 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 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.[5,6]

American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU)
AUA/SUFU recommendations state that clinicians may offer SNM as third-line treatment for carefully selected patients who have severe refractory OAB symptoms or 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.[7]

Periurethral Bulking Agents
Urethral bulking agent (UBA) therapy, also known as periurethral injection therapy, is rarely used as a primary treatment for stress urinary 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.[8] 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.[3,9,10,11]

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.[3,9,10,11]

United States Food and Drug Administration (FDA) approved products for periurethral injection therapy include[19,20,21,22]

- Carbon-coated zirconium oxide beads suspended in a water-based gel (Durasphere EXP, FDA approved in 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.[8]

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.[9]

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 2024, 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	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, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array

HCPCS Codes	Description
A4290	Sacral nerve stimulation test lead, each
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

HCPCS Codes	Description
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, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

Reviews, Revisions, and Approvals	Date	Approval Date
Policy adopted from Health Net NMP#215, Urinary Incontinence Devices and Treatments. Formerly, up to 5 UBA treatments were noted as covered, and beyond that would be considered a treatment failure. However, since this specific information could not be found in references, it was removed.	04/17	04/17
References reviewed and updated. Added ICD-10: R35.0.	02/20	03/20
Annual reviewed completed; references reviewed and updated, codes reviewed. Specialist reviewed. Replaced "member" with "members/enrollees" in all instances.	03/21	03/21
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." Added HCPCS code A4290. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." References reviewed, updated and reformatted. Reviewed by specialist.	11/21	11/21
Annual review. Updated criteria section to clarify abbreviations. Criteria I.D. # 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.	11/22	11/22
Removed continence support pessaries from criteria I.D.1. Revised order in which conservative therapies are listed in I.D.2.	06/23	06/23

Reviews, Revisions, and Approvals	Date	Approval Date
Annual review. Added note under Description to refer to CP.MP.133 Posterior Tibial Nerve Stimulation for Voiding Dysfunction for posterior tibial nerve stimulation treatment for urinary incontinence. Updated criteria I.B. from, urinary retention have been present for at least 12 months, to, urinary retention have been present for at least 6 months. Minor rewording in Criteria with no clinical significance. Background updated with no impact on criteria. References reviewed and updated. Reviewed by external specialist.	11/23	11/23
Annual review. Added language to Criteria I. regarding a United Sates Food and Drug Administration (FDA) approved device. Minor rewording in Criteria I.B. with no impact to criteria. Added language to Criteria II. to include an FDA approved device. Updated verbiage in Criteria II.B. to state "at least" a 50% reduction in incontinence. Minor rewording in Criteria III. with no impact on criteria. Reworded Criteria III.B. for flow and changed Kegel exercises to pelvic floor therapy. Changed "patient" to "Member/enrollee" in Criteria III.C. References reviewed and updated.	11/24	11/24
Annual review. Comment after III.C. removed. Misc. edits to background with no impact on criteria. References reviewed and updated. Reviewed by external specialist.	11/25	11/25

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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.

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Note: For Medicaid members/enrollees, 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.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.