

Clinical Policy: Urinary Incontinence Devices and Treatments

Reference Number: CP.MP.142

Last Review Date: 03/18

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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.

Note: For biofeedback treatment for urinary incontinence, please refer to CP.MP.168 Biofeedback.

Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation® that SNM is **medically necessary** to treat lower urinary tract dysfunction when all of the following criteria are met:
 - A. Symptoms of incontinence have been present for at least 12 months and have resulted in significant disability, such as the limited ability to work or participate in activities outside of the home;
 - B. Diagnosis is non-obstructive urinary retention;
 - C. Incontinence is not related to a neurologic condition;
 - D. Conservative measures such as bladder training, pelvic floor physical therapy with biofeedback, and pharmacologic treatment have failed;
 - E. A percutaneous stimulation test has provided a 50% reduction in incontinence symptoms prior to permanent device implantation.

- II. It is the policy of health plans affiliated with Centene Corporation that injection of U.S. FDA approved UBAs is **medically necessary** when all of the following criteria are met:
 - A. Diagnosis of persistent or recurrent stress urinary incontinence due to intrinsic sphincter deficiency, or post traumatic or surgical injury;
 - B. Conservative management such as Kegel exercises, biofeedback, electrical stimulation, and pharmacotherapies have failed;
 - C. Patient is unable to tolerate surgery.

*A recurrence of incontinence following a successful treatment series (i.e., 6-12 months previously, may benefit from additional treatments).¹⁰

- III. It is the policy of health plans affiliated with Centene Corporation that autologous fat as a UBA injection, procedures that are not FDA approved, and any other circumstances than those specified above are considered **investigational**.

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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, 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 sacral neuromodulation is that it is tested for potential success prior to moving on to long-term therapy. 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 urgency urinary incontinence and overactive bladder, but it is reasonable to try prior to more invasive and permanent solutions.

A prospective study has demonstrated that sacral nerve stimulation for refractory urinary urge incontinence had a positive benefit of 30.8 months.⁸ A meta-analysis noted that sacral neuromodulation is an effective therapy for the treatment of nonobstructive urinary retention.¹² 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 Urologic Association

Clinicians may offer SNM 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. Recommendation (Grade C; benefits outweigh risk/burdens).⁵

National Institute for Health and Care Excellence

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

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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.¹¹

Periurethral Bulking Agents

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 are unable to tolerate surgical procedure. 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 4 9 10}

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 4 9 10}

U.S. FDA approved products for periurethral injection therapy include:

- Carbon-coated zirconium oxide beads suspended in a water-based gel (Durasphere EXP, FDA approved 1999)
- Crosslinked polydimethylsiloxane (Macroplastique, FDA approved 10/30/2006)
- Calcium hydroxylapatite suspended in a water and glycerin gel (Coaptite, 11/10, 2005)

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.

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.³

Coding Implications

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| CPT® Codes | Description |
|------------|--|
| 51715 | Endoscopic injection of implant material into the submucosal tissue of the |
| 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) |

| 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 |

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

| ICD-10-CM Code | Description |
|----------------|--------------------------------------|
| N32.81 | Overactive bladder |
| N36.42 | Intrinsic sphincter deficiency (ISD) |
| N39.3 | Stress incontinence (female) (male) |
| N39.41 | Urge incontinence |
| R33.8 | Other retention of urine |

| 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 |
| Added note to refer to CP.MP.168 Biofeedback for criteria related to biofeedback for urinary incontinence. | 06/17 | |
| References reviewed and updated. | 02/18 | 03/18 |
| Reworded investigational statement in III for clarity | 04/18 | |

References

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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

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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.

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Note: For Medicaid members, 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, 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.

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