Clinical Policy: Urinary Incontinence Devices and Treatments

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Coding Implications
Revision Log

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 Pennsylvania Health and Wellness® (PHW) 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 PHW 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;

*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 PHW that for autologous fat injection, procedures that are not FDA approved, and for any other circumstances than those specified above are considered investigational.

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 Clinical 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

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
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 2017, 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
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)
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
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
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
References reviewed and updated.	04/18 PHW	
Reworded investigational statement in III for clarity. CPT and HCPS codes updated	11/18	02/19

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