

Clinical Policy: Urinary Incontinence Devices and Treatments

Reference Number: LA.CP.MP.142^c

Date of Last Revision: 02/22/23

Coding Implications

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.

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

Policy/Criteria

- I. It is the policy of Louisiana Healthcare Connections that a *trial* of Sacral neuromodulation (SNM) 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 12 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~~, continence-support pessaries and pharmacologic treatment;
 2. For non-obstructive urinary retention, pharmacologic treatment and intermittent self-catheterization, unless not well-tolerated;
- II. It is the policy of Louisiana Healthcare Connections that *permanent placement* of SNM is **medically necessary** to treat lower urinary tract dysfunction when both of the following criteria are met
 - A. Criteria in section I ~~are~~^{is} met;
 - B. A percutaneous stimulation test ~~has~~ provided a 50% reduction in incontinence, retention, or urgency/frequency symptoms prior to permanent device implantation.
- III. It is the policy of Louisiana Healthcare Connections that injection of U.S. United States Food and Drug Administration (FDA) approved urethral bulking agents (UBA)s 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.** Conservative management such as Kegel exercises, biofeedback, electrical stimulation, and pharmacotherapies have failed;
- C.** Patient is unable to tolerate surgery or does not wish to have surgery.

*A recurrence of incontinence following a successful treatment series (i.e., 6 to -12 months previously), may benefit from additional treatments. ³⁴⁹

IV. It is the policy of Louisiana Healthcare Connections 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 ~~sacral neuromodulation~~SNM is that it is tested for potential success prior to surgical implantation of a permanent device.~~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.¹

A prospective study has demonstrated that sacral nerve stimulation for refractory urinary urge incontinence had a positive benefit of 30.8 months.⁴⁸ A meta-analysis noted that sacral neuromodulation is an effective therapy for the treatment of nonobstructive urinary retention.⁵⁴² 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.^{5,6,7}

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).³⁺⁹

National Institute for Health and Care Excellence

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.¹¹

Periurethral Bulking Agents

Urethral bulking agent (UBA) therapy, also known as periurethral injection therapy, is rarely used as a primary treatment for stress urinaryurge 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.¹⁵ 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, 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.^{3-4, 9, 11-10}

United States Food and Drug Administration 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 in 1999)
- Crosslinked polydimethylsiloxane (Macroplastique, FDA approved 10/October 30, 2006)
- Calcium hydroxylapatite suspended in a water and glycerin gel (Coaptite, FDA approved November 10/11, 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.

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. ⁹³

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 2021, 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 and may not support medical necessity. 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
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

HCPCS Codes	Description
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

~~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
R35.0	Frequency of micturition

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Converted corporate to local policy.	08/15/2020	
Annual reviewed completed; references reviewed and updated, codes reviewed. 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.” Added “may not support medical necessity” to coding implications. References reviewed, updated and reformatted. Reviewed by specialist.	2/22	4/10/22
Codes reviewed and updated-removed ICD-10 table Removed references to biofeedback Updated criteria section to clarify abbreviations. Criteria I.D. # 1 updated to include continence-support pessaries as a conservative	1/23	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
<u>measure. Updated background with no impact on criteria. Removed ICD-10 codes. References reviewed and updated.</u>		

References

1. Lukacz ES. Female urinary incontinence: Treatment. UpToDate. www.uptodate.com. Published July 13, 2022. Accessed October 10, 2022.
2. Morgan DM. Stress urinary incontinence in females: Persistent/recurrent symptoms after surgical treatment. www.uptodate.com. Published April 18, 2022. Accessed October 10, 2022.
3. Gormley EA, Lightner DJ, Burgio KL, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline. *J Urol*. 2012;188(6 Suppl):2455 to 2463. doi:10.1016/j.juro.2012.09.079
4. Goldman HB, Lloyd JC, Noblett KL, et al. International Continence Society best practice statement for use of sacral neuromodulation. *Neurourol Urodyn*. 2018;37(5):1823 to 1848. doi: 10.1002/nau.23515
5. Janknegt RA, Houssouna MM, Siegel SW, et al. Long-term effectiveness of sacral nerve stimulation for refractory urge incontinence. *Eur Urol* 2001;39:101 to 106. doi:10.1159/000052420
6. Dray EV, Hall M, Covalschi D, Cameron AP. Can Urethral Bulking Agents Salvage Failed Slings? *Urology*. 2019;124:78 to 82. doi: 10.1016/j.urology.2018.09.019
7. Ghoniem G, Boctor N. (2014) Update on Urethral Bulking Agents for Female Stress Urinary Incontinence due to Intrinsic Sphincter Deficiency. *J Urol Res* 1(2): 1009. https://escholarship.org/content/qt9dt57291/qt9dt57291_noSplash_c18758fbc805379975a8761fa575c5ee.pdf. Accessed October 28, 2022.
8. Gross C, Habli M, Lindsell C, South M. Sacral neuromodulation for nonobstructive urinary retention: a meta-analysis. *Female Pelvic Med Reconstr Surg*. 2010;16(4):249 to 253. doi:10.1097/SPV.0b013e3181df9b3f
9. Zhou S, Zhang K, Atala A, et al. Stem Cell Therapy for Treatment of Stress Urinary Incontinence: The Current Status and Challenges. *Stem Cells Int*. 2016;2016:7060975. doi:10.1155/2016/7060975
10. Chung E, Lee D, Gani J, et al. Position statement: a clinical approach to the management of adult non-neurogenic overactive bladder. *Med J Aust*. 2018;208(1):41 to 45. doi:10.5694/mja16.01097
11. Lightner DJ, Gomelsky A, Souter L, Vasavada SP. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline amendment 2019. *J Urol*. 2019;202:558 to 563. doi:10.1097/JU.0000000000000309
12. American College of Obstetricians and Gynecologists. Urinary Incontinence in Women. Practice Bulletin. No. 155. <https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2015/11/urinary-incontinence-in-women>. Published November 2015 (reaffirmed 2022). Accessed October 13, 2022.
13. Lukacz ES. Urgency urinary incontinence/overactive bladder (OAB) in females: Treatment. UpToDate. www.uptodate.com. Published September 24, 2021. Accessed October 10, 2022.

14. American College of Obstetricians and Gynecologists. Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment. No. 603. <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/06/evaluation-of-uncomplicated-stress-urinary-incontinence-in-women-before-surgical-treatment>. Published June 2014 (reaffirmed 2020). Accessed October 28, 2022.
15. Gill BC. Injectable Bulking Agents for Incontinence. *MedScape*. <https://emedicine.medscape.com/article/447068-overview#a1>. Published June 20, 2018. Accessed October 28, 2022.
16. National Institute for Health and Care Excellence. Sacral nerve stimulation for urge incontinence and urgency-frequency - Interventional procedures guidance [IPG64]. <https://www.nice.org.uk/guidance/ipg64>. Published June 23, 2004. Accessed October 28, 2022.
17. Siegel S, Noblett K, Mangel J, et al. Results of a prospective, randomized multicenter study evaluating sacral neuromodulation with InterStim therapy compared to standard medical therapy at 6-months in subjects with mild symptoms of overactive bladder. *Neurol Urodyn*. 2015;34(3):224 to 230. doi:10.1002/nau.22544
18. Kirchin V, Page T, Keegan PE, et al. Urethral injection therapy for urinary incontinence in women. *Cochrane Database Syst Rev*. 2017;7(7):CD003881. Published 2017 Jul 25. doi:10.1002/14651858.CD003881.pub4
19. Siddiqui ZA, Abboudi H, Crawford R, Shah S. Intraurethral bulking agents for the management of female stress urinary incontinence: a systematic review. *Int Urogynecol J*. 2017;28(9):1275 to 1284. doi:10.1007/s00192-017-3278-7
- ~~1. American College of Obstetricians and Gynecologists. Urinary Incontinence in Women. Practice Bulletin Number 155. Published November 2015 (Reaffirmed 2019). Accessed October 8, 2021~~
- ~~2. American College of Obstetricians and Gynecologists. Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment. No 603. Published June 2014 (Reaffirmed 2020). Accessed October 8, 2021.~~
- ~~3. Burkhard FC, Lucas MG, Berghmans LC, et al. EAU guidelines on urinary incontinence in adults. Report, European Association of Urology, March 2018.~~
- ~~4. Chung E, Lee D, Gani J, et al. Position statement: a clinical approach to the management of adult non-neurogenic overactive bladder. *Med J Aust*. 2018;208(1):41-45.~~
- ~~5. Dray EV, Hall M, Covalschii D, Cameron AP. Can urethral bulking agents salvage failed slings? *Urology*. 2019;124:78-82. doi: 10.1016/j.urology.2018.09.019.~~
- ~~6. Ghoniem G, Boctor N. Update on Urethral Bulking Agents for Female Stress Urinary Incontinence due to Intrinsic Sphincter Deficiency. *J Urol Res*. 1(2): 1009.~~
- ~~7. Gill BC. Injectable Bulking Agents for Incontinence. MedScape. June 20, 2018. Accessed October 12, 2021. <https://emedicine.medscape.com/article/447068-overview#a1>~~
- ~~8. Goldman HB, Lloyd JC, Noblett KL, et al. International Continence Society best practice statement for use of sacral neuromodulation. *Neurol Urodyn*. 2018;37(5):1823-1848. doi: 10.1002/nau.23515.~~
- ~~9. Lightner DJ, Gomelsky A, Souter L, Vasavada SP. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults. AUA/SUFU guideline amendment 2019. *J Urol* 2019; 202: 558. doi:10.1097/JU.0000000000000309~~

10. Gormley EA, Lightner DJ, Burgio KL, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline. *J Urol*. 2012;188(6 Suppl):2455–2463. doi:10.1016/j.juro.2012.09.079
11. Gross C, Habli M, Lindsell C, et al. Sacral neuromodulation for nonobstructive urinary retention; a meta-analysis. *Female Pelvic Med Reconstr Surg*. 2010;16(4):249–253. doi:10.1097/SPV.0b013e3181df9b3f
12. Janknegt RA, Houssouna MM, Siegel SW, et al. Long-term effectiveness of sacral nerve stimulation for refractory urge incontinence. *Eur Urol* 2001; 39:101–6.
13. Lukacz ES. Treatment of urgency incontinence/overactive bladder (OAB) in females. UpToDate. Brubaker L, Schmader KE (Eds) UpToDate. www.uptodate.com published September 24, 2021. Accessed October 8, 2021.
14. Lukacz ES. Treatment of urinary incontinence in females. UpToDate. www.uptodate.com Published October 19, 2020. Accessed October 8, 2021.
15. Morgan DMM Stress Urinary Incontinence in Women: Persistent/Recurrent Symptoms After Surgical Treatment. UpToDate. www.uptodate.com Published May 7, 2021. Accessed October 8, 2021.
16. National Institute for Health and Care Excellence (NICE). Sacral nerve stimulation for urge incontinence and urgency frequency. June 23, 2004. Accessed October 11, 2021.
17. Siegel S, Noblett K, Mangel J, et al. Results of a prospective, randomized multicenter study evaluating sacral neuromodulation with InterStim therapy compared to standard medical therapy at 6 months in subjects with mild symptoms of overactive bladder. *Neurol Urodyn*. 2015;34(3): 224–230. doi:10.1002/nau.22544
18. Kirchin V, Page T, Keegan PE, et al. Urethral injection therapy for urinary incontinence in women. *Cochrane Database Syst Rev*. Published 2017 Jul 25. doi: 10.1002/14651858.CD003881.pub4
19. Siddiqui ZA, Abboudi H, Crawford R, Shah S. Intraurethral bulking agents for the management of female stress urinary incontinence: a systematic review. *Int Urogynecol J*. 2017;28(9):1275–1284. doi:10.1007/s00192-017-3278-7

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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 LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. 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.

©2020 Louisiana Healthcare Connections. All rights reserved. All materials are exclusively owned by Louisiana Healthcare Connections and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Louisiana Healthcare Connections. You may not alter or remove any trademark, copyright or other notice contained herein. Louisiana Healthcare Connections is a registered trademark exclusively owned by Louisiana Healthcare Connections.