Clinical Policy: Bladder and Sacral Nerve Stimulation

Reference Number: IL.CP.MP.527 Coding Implications
Last Review Date: 03/22 Revision Log

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

Description

Members who have persistent urgency incontinence symptoms despite an adequate trial of initial treatments and pharmacotherapies, or who are unable to tolerate [or fail] pharmacologic therapy, warrant referral to a specialist to discuss further options for management with third-line therapies (i.e. Sacral Nerve Stimulator (SNS) or Percutaneous Tibial Nerve Stimulator (PTNS).

Overactive Bladder Syndrome (OAB) is a term used to describe urinary urgency, usually with urinary frequency and nocturia, with or without urinary incontinence**. Sacral Nerve Stimulator (SNS)** is a minimally invasive electrical stimulation option to treat OAB symptoms. It is also called **sacral neuromodulation (SNM). Percutaneous Tibial Nerve Stimulator (PTNS)** deliver retrograde access to the sacral nerve through percutaneous stimulation of the tibial nerve.

Policy/Criteria

I. It is the policy of MeridianHealth affiliated with Centene Corporation® that sacral nerve stimulation is **medically necessary** for the following indications:

II. **Sacral Nerve Stimulation (SNS (or SNM)):** Is potentially medically necessary for the treatment an overactive bladder. SNS is considered a third and final line of therapy for following diagnoses:

A. Urinary urge incontinence; ***or*** B.
Urinary urge frequency
C. And **all** the following:

i. The member symptoms of urge incontinence or frequency symptoms have lasted for at least 6 months and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member's ability to participate in ADLs)
ii. Active urinary tract infections and anatomical abnormalities of the lower urinary tract have been excluded as a source of urinary dysfunction
iii. The aforementioned diagnoses must be made by urodynamic testing with or without EMG evaluation of the bladder iv. First **and** Second-line therapies have failed

III. **First-Line Therapy (also known as pelvic floor rehabilitation)**

A. Lifestyle modifications-dietary changes-avoidance of alcohol, caffeine intake, avoidance of carbonated beverages.
B. Bladder training- timed voiding with voiding diary for at least 6 weeks.
C. Pelvic floor muscle exercises for at least 6 weeks.
D. Fluid management - If patient was drinking excessive fluid intake, decrease fluid intake to < 64 oz/day and decrease fluid intake before bed if nocturia present.

IV. **Second-Line Therapy -** Consists of trial and failure of at least **two FDA approved** oral pharmacological anti-muscarinic agents or **Meridian's formulary**. A. Pharmacological trials **must** consist of the following:

i. Attempts of dose and delivery modulation (e.g.5 vs. 10mg
ii. pill vs. patch, immediate vs. extended release preparations)
iii. Trial must have been attempted for at least 6 weeks per medicaine tried iv. A second pharmacologic agent can be tried after 6 weeks of no improvement with dose adjusting after every 2 weeks. (If some improvement is noted, it can take up to 12 weeks to get maximum efficacy)
v. Constipation and dry mouth should be addressed/treated before abandoning anti-muscarinic treatments.

V. **Third-Line Therapy**

A. **Temporary/Test Stimulation:** Considered medically necessary when an adequate trial of first and second line therapies have failed. (Note: Sequential stimulation of the right and left sides (no more than 6 stimulations total) is acceptable).

B. **Permanent Placement:** A member may be eligible for permanent placement if **all** of the following criteria are met:

i. The temporary SNS trial was successful as defined by voiding diaries completed by member over at least 2 weeks:
    1. **Urinary urge incontinence:** At least 50% reduction in one of the following: daily incontinence episodes, severity of the episodes or the number of pads/diapers used per day
    2. **Urinary urge/frequency:** At least 50% reduction in one of the following: number of voids daily, volume per void and frequency per void
ii. The device must be FDA approved and used according to FDA iii. The member is 16 years or older

VI. **SNS for the Treatment of Non-obstructive Urinary Retention -** Is medically necessary for treatment of non-obstructive urinary retention. A member is eligible when **all** of the following criteria are met:

A. **Temporary/Test Stimulation:**

i. The member has experienced urinary retention for at least 12 months as defined as PVR > 30% of total bladder capacity
ii. The condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member's ability to participate in daily activities)
iii. There is concern for adverse outcomes without treatment including risk of infection and increased bladder pressures which are felt to cause risks of upper tract injury and impairment of renal function
iv. Pharmacotherapies (e.g., alpha blockers and cholinergics when deemed appropriate, and antibiotics for urinary tract infections) have failed or are not well-tolerated
v. Intermittent catheterization has failed or is not well-tolerated

vi. All other causes of urinary retention have been ruled out (see non-covered conditions) including side effects of medicines, constipation, etc. B. **SNS Removal:**

i. SNS removal is medically necessary even when the initial implantation of the SNS was not indicated

VII. **Percutaneous Tibial Nerve Stimulator (PTNS)**

A. Will be reviewed with **Centene Clinical Policy: CP.MP 133**

i. Posterior Nerve Stimulation for Voiding Dysfunction (centene.com)

VIII. **Absolute Contraindications**

A. Meridian the SNS Device experimental and investigational for members with the following diagnoses:

i. Members with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) which are associated with secondary manifestations of the above three indications. ii. Neurogenic urinary retention

iii. Pregnancy
iv. Diabetes
v. Interstitial cystitis
vi. Chronic Pelvic pain
vii. Fowler's syndrome
viii. Multiple sclerosis
ix. Patients with mechanical obstructions/strictures or cancer

Of Note: The American Urologic Society considers Botulism Toxin injections a third-line treatment for urge incontinence, urgency/frequency, as well. Members may possibly be approved for these q 3 months injections with a PA through Meridian Rx.

Coding Implications

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CPT®* Codes	Description

HCPCS ®* Codes	Description

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date		9/27/13
Annual Review with no changes		03/22

References

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3. Herbison, G.P, Arnold, E.P. (2009, April 15). Electrical Stimulation of Nerve with Permanently Implanted Devices for Adults with Abnormal Urine Storage or Voiding. Cochrane Summaries. http://www.cochrane.org/CD004202/INCONT_electricalstimulation-of-nerves-with-permanently-implanted-devices-for-adults-with-abnormalurine-storage-or-voiding
4. Johnson, Theodore M. (2015) Nocturia: Clinical presentation, diagnosis, and treatment. Up to Date. http://www.uptodate.com/contents/nocturia-clinical-presentation-diagnosisand-treatment
5. Peters KM, Carrico DJ, Wooldridge LS, et al. Percutaneous tibial nerve stimulation for the long-term treatment of overactive bladder: 3-year results of the STEP study. J Urol.

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7. American Urological Association/SUFU guideline: Published 2012;Amended 2014
8. ACOG;AGUS Practice Bulletin Number 155, 11/2015 "Urinary Incontinence in Women." Updated 2018.
9. Hayes, Percutaneous Tibial Nerve Stimulation for the Treatment of Lower Urinary Tract Dysfunction. Annual Review: Nov, 15, 2016.
10. Hayes Review: Implantable Sacral Nerve Stimulation for Urinary Voiding Dysfunction. **Annual Review:** May 22, 2014. **Report Archived On:** Aug 12, 2015.
11. Up To Date: Treatment of urgency incontinence/overactive bladder in females: Literature review current through: July 2020. This topic last updated: Feb 18, 2020.
12. Up To Date: Lower urinary tract symptoms in men. Literature review current through: Jul 2020. This topic last updated: Jul 13, 2020.
13. State of Illinois Contract between the Department of Healthcare and Family Services and Meridian Health Plan of Illinois, 2018-24-601, Preauthorization and Concurrent Review Requirements, 1.1.2.3.3

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

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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.

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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.