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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Urinary Incontinence Policy

Indication/Usage:

Urinary incontinence is a significant problem, affecting tens of millions of Americans. Patients may not report incontinence to their primary care providers due to embarrassment or misconceptions regarding treatment. Since incontinence is often treatable, it is imperative the health care professional be adept at identifying patients who might benefit from treatment. Since the treatment of incontinence varies depending on the etiology, the aim of evaluation is to identify the specific type of incontinence. Etiology Urinary incontinence is generally the result of either bladder or urethral dysfunction (American Urological Association, 2016)

Bladder Dysfunction

1. Urge Incontinence
    - detrusor over activity
    - detrusor over activity of non-neurogenic origin
    - detrusor over activity of neurogenic origin
    - poor compliance

2. Overflow incontinence (U.S. Department of Health and Human Services, 2017
    - anatomic
    - enlarged prostate
    - diabetes
    - spinal cord injury

Urethral Dysfunction

1. Stress incontinence
    - anatomic (due to mobility of the bladder neck)
    - intrinsic sphincter deficiency (due to bladder neck dysfunction)

2. Functional Incontinence
3. Mixed Incontinence (Stress and urge incontinence)

Medical Indications for Authorization
Commercial Members

1. Biofeedback therapy – SummaCare considers biofeedback medically necessary for the treatment of urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training and is delivered by a practioner in an office or facility setting.

2. Sacral Nerve Stimulation – SummaCare considers sacral nerve stimulation medically necessary for the treatment of urinary urge incontinence, urgency-frequency syndrome, and non-obstructive urinary retention when the following criteria are met
    - The member has experienced urge UI, non-obstructive urinary retention, **or** symptoms of urge-frequency 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 daily activities); ***and***
    - Pharmacotherapies (at least 2 different anti-cholinergic drugs or an anti-cholinergic and a beta3 adrenergic receptor agonist for UI or urge frequency or alpha blockers and antibiotics for urinary tract infections for urinary retention), as well as behavioral treatments for urge frequency (e.g., pelvic floor exercise, biofeedback, timed voids, and fluid management) **or**
    - Intermittent catheterization non-obstructive urinary retention have failed or are not well-tolerated ***and***
    - Test stimulation provides at least 50 % decrease in symptoms

3. Percutaneous Tibial Nerve Stimulation (PTNS)- SummaCare considers posterior tibial nerve stimulation medically necessary when the following criteria are met

    - The member has urgent urinary incontinence that has limited the member's ability to participate in daily activities.
    - The member has failed conservative therapy to include:

        ○ At least 2 different anticholinergics or an anticholinergic ○

        Tricycle antidepressant ○ Fluid management ○ Pelvic floor

        exercise ○ Times voiding ○ biofeedback

    - Patients must report an improvement in symptoms of urinary frequency, nocturia, and/or urinary urgency within 6 weeks (i.e., 6 sessions) of initiation of PTNS for continued coverage.
    - After the initial 12 sessions, treatments will be allowed at a frequency of 1 every month for up to a total of two years. The 2-year time period begins with the initiation of PTNS treatment. Subsequent treatment will not be covered.
    - After an initial ultrasound bladder evaluation, repeated ultrasound bladder evaluations will only be allowed if there is appropriate documentation of the medical necessity of this testing.

4. Non-Implantable Pelvic Floor Electrical Stimulator - SummaCare considers Non-Implantable Pelvic Floor Electrical Stimulator medically necessary when the following criteria are met
    - Pelvic floor electrical stimulation with a non-implantable stimulator is covered for the treatment of stress and/or urge urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training.
    - A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.

5. Mechanical/Hydraulic Incontinence Control Devices - SummaCare considers Mechanical/Hydraulic Incontinence Control Devices medically necessary when the following criteria are met.
    - For the management of urinary incontinence in patients with permanent anatomic and neurologic dysfunctions of the bladder. This class of devices achieves control of urination by compression of the urethra. The materials used and the success rate may vary somewhat from device to device.

6. Collagen Implant / bulking agents - SummaCare considers collagen implants medically necessary for members with stress urinary incontinence due to ISD when the following criteria is met after failure of conservative management. (E.g. kegal exercises, pharmacotherapies or biofeedback)
    - Male or female patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;

- Male or female patients with acquired sphincter weakness secondary to spinal cord lesions;
- Male patients following trauma, including prostatectomy and/or radiation; and
- Female patients without urethral hypermobility and with abdominal leak point pressures of 100 cm H2O or less.

Patients whose incontinence does not improve with 5 injection procedures (5 separate treatment sessions) are considered treatment failures, and no further treatment of urinary incontinence by collagen implant is covered.

Patients who have a reoccurrence of incontinence following successful treatment with collagen implants in the past (e.g., 6-12 months previously) may benefit from additional treatment sessions. Coverage of additional sessions may be allowed but must be supported by medical justification.

Medicare Members CMS NCD ID 30.1.1 Biofeedback Therapy for the Treatment of Urinary Incontinence Indications and Limitations of Coverage

This policy applies to biofeedback therapy rendered by a practitioner in an office or other facility setting. Biofeedback is covered for the treatment of stress and/or urge incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training. Biofeedback is not a treatment, per se, but a tool to help patients learn how to perform PME. Biofeedback assisted PME incorporates the use of an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone, in order to improve awareness of pelvic floor musculature and to assist patients in the performance of PME.

A failed trial of PME training is defined as no clinically significant improvement in urinary incontinence after completing 4 weeks of an ordered plan of pelvic muscle exercises to increase periurethral muscle strength. Contractors may decide whether or not to cover biofeedback as an initial treatment modality. Home use of biofeedback therapy is not covered.

NCD ID 230.18 Sacral Nerve Stimulation for Urinary Incontinence Indications and Limitations of Coverage

Effective January 1, 2002, sacral nerve stimulation is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention. Sacral nerve stimulation involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. Both the test and the permanent implantation are covered.
The following limitations for coverage apply to all three indications:

- Patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.

- Patients 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 are excluded.
- Patient must have had a successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through voiding diaries.
- Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated

NCD 230.8 Non-Implantable Pelvic Floor Electrical Stimulator Indications and Limitations of Coverage

Pelvic floor electrical stimulation with a non-implantable stimulator is covered for the treatment of stress and/or urge urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training.

A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.

NCD ID 230.10 Incontinence Control Devices Indications and Limitations of Coverage

Mechanical/Hydraulic Incontinence Control Devices

- Mechanical/hydraulic incontinence control devices are accepted as safe and effective in the management of urinary incontinence in patients with permanent anatomic and neurologic dysfunctions of the bladder. This class of devices achieves control of urination by compression of the urethra. The materials used and the success rate may vary somewhat from device to device. Such a device is covered when its use is reasonable and necessary for the individual patient.

Collagen Implant

- A collagen implant, which is injected into the submucosal tissues of the urethra and/or the bladder neck and into tissues adjacent to the urethra, is a prosthetic device used in the treatment of stress urinary incontinence resulting from intrinsic sphincter deficiency (ISD). ISD is a cause of stress urinary incontinence in which the urethral sphincter is unable to contract and generate sufficient resistance in the bladder, especially during stress maneuvers.

Prior to collagen implant therapy, a skin test for collagen sensitivity must be administered and evaluated over a 4-week period.

In male patients, the evaluation must include a complete history and physical examination and a simple cystometrogram to determine that the bladder fills and stores properly. The patient then is

asked to stand upright with a full bladder and to cough or otherwise exert abdominal pressure on his bladder. If the patient leaks, the diagnosis of ISD is established.

In female patients, the evaluation must include a complete history and physical examination (including a pelvic exam) and a simple cystometrogram to rule out abnormalities of bladder compliance and abnormalities of urethral support. Following that determination, an abdominal leak point pressure (ALLP) test is performed. Leak point pressure, stated in cm H2O, is defined as the intra-abdominal pressure at which leakage occurs from the bladder (around a catheter) when the bladder has been filled with a minimum of 150 cc fluid. If the patient has an ALLP of less than 100 cm H2O, the diagnosis of ISD is established.

To use a collagen implant, physicians must have urology training in the use of a cystoscope and must complete a collagen implant training program.

Coverage of a collagen implant, and the procedure to inject it, is limited to the following types of patients with stress urinary incontinence due to ISD:

- Male or female patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;
- Male or female patients with acquired sphincter weakness secondary to spinal cord lesions;
- Male patients following trauma, including prostatectomy and/or radiation; and
- Female patients without urethral hypermobility and with abdominal leak point pressures of 100 cm H2O or less

Patients whose incontinence does not improve with 5 injection procedures (5 separate treatment sessions) are considered treatment failures, and no further treatment of urinary incontinence by collagen implant is covered. Patients who have a reoccurrence of incontinence following successful treatment with collagen implants in the past (e.g., 6-12 months previously) may benefit from additional treatment sessions. Coverage of additional sessions may be allowed but must be supported by medical justification.

Limitations

Renessa - Radiofrequency micro remodeling utilizes low temperatures through an in-office transurethral procedure to denature collagen in microscopic sites, resulting in a change in luminal function without tissue necrosis or vascular or nerve damage. SummaCare considers Renessa and similar devices investigational and not eligible for coverage.

Extracorporeal Magnetic Innervation for treatment of stress incontinence. Extracorporeal Magnetic Stimulation (EMS) involves pulsed magnetic stimulation of the sacral nerves and/or pudendal nerves, with the goal of rehabilitating the pelvic floor musculature to reduce urinary incontinence. o CMS has issued no NCD addressing EMS for urinary incontinence. SummaCare considers EMS investigational and therefore not eligible for coverage.

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

https://www.cms.gov/medicare-coverage-database/view/ncacal-decisionmemo.aspx?proposed=N&ncaid=12

https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=249

https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=231

https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=241

American Urological Association. (2016, 7). American Urological Association Education. Retrieved 8 25, 2017, from auanet.org: http://www.auanet.org/education/auauniversity/medicalstudenteducation/medicalstudentcurriculum/urinary-incontinence

Hayes Inc. (2012, 3 13). Transurethral Radiofrequency Micro-Remodeling Using the Renessa System for Female Stress Urinary Incontinence. Retrieved 8 24, 2017, from HayesInc.com: https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=5603&searchStore=%24search_type%3Dall%24icd%3D%24keywords%3Drenessa%24status%3Dall%24page%3D1%24from_date%3D%24to_date%3D%24report_type_options%3D%24technology_type_options%3D%24or

Hayes Inc. (2011, 5 2). Hayes Medical Technology Directory. Retrieved 8 2017, 2017, from Hayesinc.com: https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=1892&&sectionSelector=ExecutiveSummary

Hayes, Inc. (2016, November 15). Medical Technology Directory. Retrieved November 1, 2017, from Hayesinc.com: https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=17376&&sectionSelector=HayesRating

U.S. Department of Health and Human Services. (2017, July 24). National Institute on Aging. Retrieved September 14, 2017, from NIH National Institute on Aging: https://www.nia.nih.gov/health/urinary-incontinence-older-adult

California Technology Assessment Forum (CTAF). Biofeedback as an adjunct to pelvic floor muscle exercises for stress urinary incontinence in women. Technology Assessment. San Francisco, CA: CTAF; June 21, 2006.

Assessment and diagnosis. In: Lucas MG, Bedretdinova D, Bosch JLHR, Burkhard F, Cruz F, Nambiar AK, de Ridder DJMK, Tubaro A, Pickard RS. Guidelines on urinary incontinence. Arnhem, the Netherlands: European Association of Urology (EAU); March 2013.

Lapitan MC, Cody DJ, Grant AM. Open retropubic colposuspension for urinary incontinence in women. Cochrane Database Syst Rev. 2009; (4):CD002912.

Leizour B, Chevrot A, Wagner L, et al. Adjustable retropubic suburethral sling Remeex®in the treatment of male stress urinary incontinence: One-year results. Prog Urol. 2017; 27(4):238-243.

Agency for Healthcare Policy and Research (AHCPR). Urinary incontinence in adults. Clinical Practice Guideline. AHCPR Pub. No. 92-0038. Rockville, MD: AHCPR; March 1992.

Angioli R, Muzii L, Zullo MA, et al. Use of bulking agents in urinary incontinence. Minerva Ginecol. 2008; 60(6):543-550