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Developed By: Medical Criteria Committee	

Csaba Mera, MD.

Approved: Csaba Mera, MD

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Description:

A number of procedures have been investigated for the treatment of urinary incontinence, including pelvic floor muscle exercises, behavioral therapy, sacral nerve stimulation, pelvic floor stimulation, surgery, and radiofrequency energy.

InterStim Continence Control Therapy is **sacral nerve stimulation** that involves the implantation, into the lower back, of electrical leads that are in contact with the sacral nerve root. The wire leads extend through an incision in the abdomen and are connected to an inserted pulse generator to deliver controlled electrical impulses. The physician programs the pulse generator and the individual is able to switch the pulse generator on and off.

An **artificial urinary sphincter** is a device that involves an inflatable cuff that fits around the urethra. A balloon regulates the pressure of the cuff and a bulb controls inflation and deflation of the cuff. The balloon is surgically places and the control pump is typically placed in the scrotum for men and the labia for women. The cuff is inflated to prevent incontinence and deflated to allow the patient to urinate.

Injectable bulking agents may be effective in decreasing urinary incontinence in men and women with intrinsic sphincter disorder. The bulking agent increases bladder-outlet resistance and/or increases urethral length. The agent is injected into the submucosal tissues of the urethra or bladder neck and/or into the tissues adjacent to the urethra. The injections increase tissue bulk, thereby increasing outlet resistance.

Pelvic floor stimulation involves the electrical stimulation of pelvic floor muscles using either a probe wired to a device for controlling the electrical stimulation, or extracorporeal pulse magnetic innervation. Innova is a commonly used electrical stimulator that consists of a battery-operated stimulator with a vaginal or rectal electrode. Treatment is performed in the privacy of the patient's home. Extracorporeal Magnetic Innervation Therapy (ExMI) is a noninvasive conservative treatment for urinary incontinence in adult women. This therapy utilizes a changing magnetic field to induce electrical depolarization of nerves and muscles of the pelvic floor. The use of this device consists of a patient sitting fully clothed in a specialized chair in which the perineum rests on the central axis of a pulsing magnetic field.

Radiofrequency energy has been investigated as a technique to shrink and stabilize the endopelvic fascia or the urethra. The SURx Transvaginal System is a radiofrequency device that has been specifically designed as a transvaginal treatment of urinary stress incontinence. The Renessa System is a non-surgical radiofrequency device that uses a balloon catheter system to deliver low temperature radiofrequency energy to the submucosa of the bladder neck and urethra. The controlled heat applied by a radiofrequency device, causes the tissue in the lower urinary tract to become firmer after healing and therefore, increases resistance to involuntary leakage.

Criteria:

- I. **Sacral nerve stimulation** will be covered to plan benefits for the treatment of urinary incontinence when **all** of the following criteria are met:
 - A. Documentation of 12 months of urinary incontinence that includes urge incontinence, nonobstructive urinary retention, or symptoms of urgency/frequency; **and**
 - B. Failure of conservative treatments including medications, Kegel exercises, and behavior modification; **and**
 - C. Adequate bladder capacity and a normal urinary tract; **and**

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- D. Member is able to operate the implantable pulse generator; **and**
- E. A trial of the device has provided at least 50% decrease in incontinence symptoms. (A trial of sacral nerve stimulation is considered medically necessary for members who meet criteria 1-4 above).

NOTE: Sacral nerve stimulation is contraindicated for patients who have not demonstrated an appropriate response to test stimulation, are unable to operate the neurostimulator, individuals who are pregnant or less than 16 years of age. Sacral nerve stimulation is not medically appropriate for individuals with mechanical obstruction, cancer, urethral stricture, or for persons with stress incontinence due to specific neurological diseases (e.g. diabetes with peripheral nerve involvement).

II. **Artificial Urinary Sphincters** will be covered to plan limitations for the treatment of urinary incontinence due to intrinsic urethral sphincter deficiency when **any** of the following criteria are met:

- A. Member is 6 or more months post-prostatectomy and has not had improvement in the severity of urinary incontinence despite trying pharmacological therapy and behavior modification; **or**
- B. Member has epispadias-exstrophy and has not had success with bladder neck reconstruction surgery; **or**
- C. Member is a woman with intractable urinary incontinence who has failed behavioral modification, pharmacological therapy, and other surgical treatments; **or**
- D. Member is a child with intractable urinary incontinence due to intrinsic urethral sphincter deficiency and has been refractory to behavioral modification or pharmacological therapy and is an unsuitable candidate for other surgical procedures for the correction of the urinary incontinence.

III. **Periurethral Injections of Bulking Agents** will be covered to plan limitations when the following criteria is met:

- A. The bulking agent is cleared by the FDA for urinary incontinence; **and**
- B. Member has urinary incontinence resulting from intrinsic sphincter deficiency that is refractory to conservative management (e.g. Kegel exercises)

NOTE: If incontinence does not improve after 3 treatments with bulking agents, treatment is considered ineffective and further treatment with bulking agents is not considered medically necessary.

Services Not Covered:

1. **Innova** and **ExMI**, or similar electrical or electromagnetic pelvic floor stimulators, are not covered by ODS. These therapies are considered experimental and investigational, as they are not supported by peer-reviewed medical literature, medical evidence, or appropriately conducted clinical trials.
2. Radiofrequency energy (**SURx**, **Relessa System**, etc.) for the treatment of stress urinary incontinence is not covered by ODS. This type of treatment is considered experimental and investigation because its effectiveness for this indication has not been established.

Information to be Submitted with Pre-Authorization Request:

Chart notes from the treating physician documenting history of incontinence and treatment tried. For review of sacral nerve stimulators, 12 months of chart notes from the treating physician are required, documenting that the above criteria has been met.

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Applicable CPT/HCPC:

Note: this list may not be all inclusive

51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck
53445	Insertion of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
53446	Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
53447	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session
53448	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff through an infected field at the same operative session including irrigation and debridement of infected tissue
53449	Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
64561	Percutaneous implantation of neurostimulator electrodes; sacral nerve
64581	Implantation neurostimulator electrodes; sacral nerve
A4290	Sacral nerve stimulation test lead, each
C1815	Prosthesis, urinary sphincter (implantable)
L8603	Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies
L8604	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml, includes shipping and necessary supplies
L8606	Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies

The following codes are not covered:

0193T	Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence
E0740	Incontinence treatment system, pelvic floor stimulator, monitor, sensor, and/or trainer

References:

<ul style="list-style-type: none"> • Siegel SW, Richardson DA, Miller KA, et al. Pelvic floor electrical stimulation for the treatment of urge and mixed urinary incontinence in women. Urology 1997. Vol 50: 934-940. • Richardson DA, Miller KL, Siegel ST, et al. Pelvic floor electrical stimulation: a comparison of daily and every-other-day therapy for genuine stress incontinence. Urology 1996. Vol 48: 110-118. • The Fundamentals of Pelvic Floor Stimulation. Supplied by EMPI. • Magnetic stimulation of the sacral roots for the treatment of stress incontinence: an investigational study and placebo controlled trial, Dept. of Urology, Sankraku Tokyo, Japan. Journal of Urology-2000 Oct. • Extracorporeal Magnetic Innervation (ExMI), supplied by the office of Dr H. Tirger, D.O. • Lavelle JP, Teahan S, Kim DY, et al. Medical and minimally invasive treatment of urinary incontinence. Reviews in Urology. Spring 1999;1(2):111-120. • Dmochowski RR, Avon M, Ross J, et al. Transvaginal radio frequency treatment of the endopelvic fascia: a prospective evaluation for the treatment of genuine stress urinary incontinence. J. Urol. 2003 Mar;169(3):1028-32. • Appell RA, Juma S, Wells WG, et al. Transurethral radiofrequency energy collagen microremodeling for the treatment of female stress urinary incontinence. Neurourol. Urodyn. 2006;25(4):331-6. • Gousse AE, Madjar S, Lambert MM, Fishman IJ. Artificial urinary sphincter for post-radical prostatectomy urinary incontinence: long-term subjective results. J Urol. 2001 Nov; 166(5):1755-8.

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- Montague DK, Angermeier KW, Paolone DR. Long-term continence and patient satisfaction after artificial sphincter implantation for urinary incontinence after prostatectomy. *J Urol.* 2001 Aug;166(2):547-9.
- Physician Advisors