Urinary Incontinence Treatment

Date of Origin: 07/2002 **Last Review Date: 03/25/2020** **Effective Date: 04/01/2020**

Dates Reviewed: 01/2004, 02/2005, 01/2006, 02/2007, 03/2008, 03/2009, 02/2011, 02/2012, 02/2013, 02/2014, 10/2015, 03/2016, 06/2017, 08/2018, 03/2019, 03/2020

Developed By: Medical Necessity Criteria Committee

I. 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.

Percutaneous tibial nerve stimulation with Urgent® PC by Uroplasty involves the placement of a fine needle electrode into the lower, inner aspect of the leg, near the tibial nerve. The needle electrode is connected to pulse generator that delivers an electrical pulse to the tibial nerve that travels to the sacral plexus. The sacral plexus is responsible for regulating bladder and pelvic floor function. The treatment protocol is for 12 treatments, once a week.

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 placed 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.

Posterior tibial nerve stimulation (PTNS) is a minimally invasive neuromodulation system designed to deliver retrograde electrical stimulation to the sacral nerve plexus through percutaneous of the posterior tibial nerve. PTNS is indicated for treatment of urinary urgency, urinary frequency, and urge incontinence. The specific mechanism of action of neuromodulation is unclear, although theories include improved blood flow and change in neurochemical balance along the neurons.

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.

II. Criteria: CWQI HCS-0067A and B

A. Moda Health covers 1 or more of the following:
    a. Implantation of the InterStim (Medtronic), a device for unilateral stimulation of the **sacral nerve** will be covered to plan benefits for the treatment of urge urinary incontinence or symptoms of urge-frequency when **1 or more** of the following criteria are met:
        i. A **trial** of InterStim device for sacral nerve stimulation is medically indicated when **ALL** of the following are met:
            1. Documentation of 12 months of urge urinary incontinence or symptoms of urge-frequency 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)
            2. The patient must be refractory to three month trial conventional therapy with **ALL** of the following:
                a. At least 2 different anti- cholinergic drugs or 1 anti-cholinergic and 1 beta-3 adrenergic receptor agonist

b. behavioral treatments such as pelvic floor exercise, biofeedback, timed voids, or fluid management

ii. **Permanent** placement of the InterStim device is medically indicated when **ALL** of the following criteria are met:

1. Documentation of 12 months of urge urinary incontinence or symptoms of urge-frequency 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)
2. The patient must be refractory to three month trial conventional therapy with ALL of the following:
    a. At least 2 different anti- cholinergic drugs or 1 anti-cholinergic and 1 beta-3 adrenergic receptor agonist
    b. behavioral treatments such as pelvic floor exercise, biofeedback, timed voids, or fluid management
3. A trial of the device has provided at least 50% decrease in incontinence symptoms

b. Implantation of the InterStim (Medtronic), a device for unilateral stimulation of the **sacral nerve** will be covered to plan benefits for the treatment of non-obstructive urinary retention when **1 or more** of the following criteria are met:

i. A **trial** of sacral nerve stimulation is medically indicated when **ALL** of the following are met:

1. Documentation of 12 months of urinary retention 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)
2. Pharmacotherapies (e.g. alpha blockers and cholinergics, and antibiotics for urinary tract infections) as well as intermittent catheterization have failed or are not well-tolerated

ii. **Permanent** placement of Sacral Nerve stimulation is medically indicated when **ALL** of the following criteria are met:

1. Documentation of 12 months of urinary retention 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)
2. Pharmacotherapies (e.g. alpha blockers and cholinergics, and antibiotics for urinary tract infections) as well as intermittent catheterization have failed or are not well-tolerated
3. A trial of the device has provided at least 50% decrease in residual urine volume

c. Moda Health considers removal of an InterStim device medically necessary even when the initial implantation of the InterStim was not indicated

d. The **InterStim** is considered experimental and investigational and is not covered for all other indications because its effectiveness for indications other than the ones listed above has not been established. (Note: bilateral sacral nerve stimulation is considered experimental and investigational for the treatment of urinary incontinence because the effectiveness of this approach has not yet been established).

e. **Artificial Urinary Sphincters (HCS-0067A)** is covered for the treatment of urinary incontinence due to intrinsic urethral sphincter deficiency with **1 or more of the following:**
    i. Patient 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
    ii. Patient has epispadias-exstrophy and has not had success with bladder neck reconstruction surgery
    iii. Patient is a woman with intractable urinary incontinence who has failed behavioral modification, pharmacological therapy, and other surgical treatments
    iv. Patient 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.
    v. Request for indications other than those listed above, is considered experimental and investigational because its effectiveness has not been established.
f. The requested procedure does **NOT** include **ALL** of the following as their effectiveness has not been established.
    i. Radiofrequency energy (SURx, Renessa System, etc.) for the treatment of stress urinary incontinence.
    ii. The Genityte procedure (laser therapy)
    iii. Pudendal nerve stimulation
    iv. Autologous myoblast transplantation
    v. Autologous muscle-derived cell therapy
    vi. Collagen porcine dermis mesh
    vii. Stem cell therapy
    viii. The extraurethral non-circumferential retropubic adjustable compression devices (ProACT Therapy System, Uromedica, Inc.)
    ix. Radiofrequency micro-remodeling with SURs System (paraurethral or transvaginal)
    x. The Neocontrol system, which uses extracorporeal magnetic innervation (ExMI)
    xi. Additional treatments or systems not listed above that have not been proven to be effective in evidence-based literature.

III. Information Submitted with the Prior Authorization Request:

1. Chart notes from the treating physician documenting history of incontinence and treatments
2. For review of sacral nerve stimulators, 12 months of chart notes from the treating physician are required, documenting that the above criteria are met.

IV. CPT or HCPC codes covered:

Codes	Description
64561	Percutaneous implantation of neurostimulator electrodes; sacral nerve
64581	Implantation neurostimulator electrodes; sacral nerve
A4290	Sacral nerve stimulation test lead, each
C1767	GENERATOR, NEUROSTIMULATOR (IMPLANTABLE), NON-RECHARGEABLE

C1778	LEAD, NEUROSTIMULATOR (IMPLANTABLE)
C1815	Prosthesis, urinary sphincter (implantable)
C1883	ADAPTOR/EXTENSION, PACING LEAD OR NEUROSTIMULATOR LEAD (IMPLANTABLE)
C1897	LEAD, NEUROSTIMULATOR TEST KIT (IMPLANTABLE)
L8604	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml, includes shipping and necessary supplies
L8680	IMPLANTABLE NEUROSTIMULATOR ELECTRODE, EACH
L8695	External recharging system for battery (external), for use with implantable neurostimulator, replacement only

V. CPT or HCPC codes NOT covered:

Codes	Description
53860	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

VI. Annual Review History

Review Date	Revisions	Effective Date
02/2013	Annual Review: Added table with review date, revisions, and effective date. Added percutaneous tibial nerve stimulation criteria and description.	03/1/2013
02/2014	Annual Review: No changes	02/25/2014
09/2015	Annual Review: Added ICD-9, ICD-10, HCPC, CPT, Medicare references	09/2015
03/2016	Annual Review: Deleted ICD-9 codes – updated Sacral nerve stimulation, updated Medicare references	03/23/2016
06/2017	Annual Review: Updated to new template	07/01/2017
8/2018	Annual Review: Changed percutaneous tibial nerve stimulation to posterior tibial nerve stimulation. Added description of PTNS	08/22/2018
03/2019	Annual Review: Clarified clinical requirements for sacral nerve stimulation, updated HCPC codes	04/01/2019
03/2020	Annual Review: Reorganized criteria- some procedures redirected to reference the MCG guidelines (PTNS and bulking agents).	04/01/2020
10/2020	Update: added hcpc code L8695	10/2020

VII. References

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13. The Fundamentals of Pelvic Floor Stimulation. Supplied by EMPI.
14. Centers for Medicare & Medicaid Services; Local Coverage Article: Sacral Nerve Stimulation for Urinary and Fecal Incontinence R3 (A51543); Noridian Healthcare Solutions; effective date 12/01/2011; Revision Effective Date 09/01/2014
15. Centers for Medicare & Medicaid Services; Local Coverage Determination (LCD): Wisconsin Physicians Service Insurance Corporation; Radiofrequency Treatment for Urinary Incontinence (L31615): effective date 06/15/2011; Revision Effective Date 4/1/2015; Updated 3/17/2015
16. Centers for Medicare & Medicaid Services; Local Coverage Article: Sacral Nerve Stimulation for Urinary and Fecal Incontinence R3 (A51543); Noridian Healthcare Solutions; effective date 04/20/2012; Revision Effective Date 09/01/2014; Updated 8/27/2014
17. Centers for Medicare & Medicaid Services; National Coverage Determination (NCD) for Biofeedback Therapy for the Treatment of Urinary Incontinence (30.1.1): effective date 7/01/2001; Implementation Date 7/1/2001
18. Physician Advisors

Appendix 1 – Applicable ICD-10 diagnosis codes:

Codes	Description
F98.0	Enuresis not due to a substance or known physiological condition
N30.10	Interstitial cystitis (chronic) without hematuria
N30.11	Interstitial cystitis (chronic) with hematuria
N31.2	Flaccid neuropathic bladder, not elsewhere classified
N31.8	Other neuromuscular dysfunction of bladder
N31.9	Neuromuscular dysfunction of bladder, unspecified
N32.81	Overactive bladder
N36.44	Muscular disorders of urethra
N39.3	Stress incontinence (female) (male)
N39.41	Urge incontinence
R32	Unspecified urinary incontinence
R33.9	Retention of urine, unspecified
R35.0	Frequency of micturition
R39.14	Feeling of incomplete bladder emptying
N39.42	Incontinence without sensory awareness
N39.43	Post-void dribbling
N39.45	Continuous leakage
N39.46	Mixed incontinence
N39.490	Overflow incontinence
N39.498	Other specified urinary incontinence
R39.15	Urgency of urination

Appendix 1 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):
National Coverage Determination (NCD) 30.1.1 Biofeedback Therapy for the Treatment of Urinary Incontinence	
https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=42&ncdver=1&DocID=30.1.1&kq=true&bc=gAAAABAAAAAAAA%3d%3d&	
National Coverage Determination (NCD) 230.18 Sacral Nerve Stimulation for Urinary Incontinence	
https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=249&ncdver=1&DocID=230.18&kq=true&bc=gAAAABAAAAAAAA%3d%3d&	
National Coverage Determination (NCD) 230.10 Incontinence Control Devices	

https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=241&ncdver=1&DocID=230.10&kq=true&bc=gAAAABAAAAAAAA%3d%3d&

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC