Medical and Behavioral Health Policy Manual
Section: Allied Health, Medicine
Policy Number: II-50
Effective Date: 11/23/2011

TREATMENT OF URINARY DYSFUNCTION

Description: This policy addresses the following treatments of urinary incontinence or urinary retention: periurethral bulking agents, electrical and magnetic stimulation, personal use ultrasound devices, botulinum toxin therapy, radiofrequency treatment, and percutaneous tibial nerve stimulation.

Periurethral bulking agents are substances that are injected periurethrally to increase tissue bulk as a treatment of stress incontinence. Patients receive one or several treatment sessions. A number of products have been developed and are commercially available (e.g., collagen implants, Durasphere®, Coaptite®, Macroplastique®); key factors in determining the optimal product are biocompatibility, durability, and absence of migration.

Pelvic electrical floor stimulation activates the pudendal nerve, causing contraction of smooth, striated urethral muscles and striated pelvic floor muscles. The electrical stimulation is transmitted via vaginal or anal electrodes intending to improve urethral closure and strengthen the pelvic floor muscles.

A personal use ultrasound device (e.g., BladderManager®) consists of a portable ultrasound unit with a sensor to monitor bladder fullness for individuals with spinal cord injury and others who must perform intermittent catheterization to enable catheterization to be done on the basis of bladder volume rather than on a timed schedule. This non-invasive monitoring device transmits low energy ultrasound waves which are reflected off the bladder wall. Data are processed to inform the user of current bladder volume. The user is alerted visually to the scan results by a liquid crystal display (LCD) on the unit. An audible alarm also sounds when bladder volume exceeds a preprogrammed threshold. An alarm will also sound if the user has exceeded a specified period between catheterizations or voids.

Botulinum toxin injections have been used for the management of patients with lower urinary tract dysfunctions including detrusor-sphincter dyssynergia and detrusor overactivity. Botulinum toxin is injected into the external urethral sphincter to treat detrusor sphincter dyssynergia, while intra-detrusal injection of botulinum toxin is

employed in treating detrusor overactivity and symptoms of the overactive bladder (OAB).

Magnetic stimulation [e.g., Extracorporeal Magnetic Innervation (ExMI™), NeoControl® Pelvic Floor System] in the treatment of urinary incontinence involves non-invasive electromagnetic stimulation of the pelvic floor muscles in order to rehabilitate weak pelvic muscles and restore neuromuscular control for the treatment of urinary incontinence. The electromagnetic technology for this treatment is imbedded in the seat of a specially designed chair where the patient sits, fully clothed for 20 to 30 minutes, to receive the treatment. Proposed treatment plans have specified that treatment sessions be conducted twice a week for approximately 8 weeks.

Percutaneous tibial nerve stimulation (PTNS) (e.g., Urgent® PC Neuromodulation System) is a minimally invasive treatment for patients with urinary urge incontinence, urgency-frequency, or non-obstructive urinary retention. The posterior tibial nerve is a mixed sensory-motor nerve containing fibers originating from spinal roots L4 through S3, comprising the outflow of the sacral nerves. These nerves modulate the somatic and autonomic nervous supply to the pelvic floor, directly innervating the bladder and urinary sphincter.
The procedure for PTNS consists of the insertion of a needle above the medial malleolus into the posterior tibial nerve followed by the application of low-voltage (10mA, 1–10 Hz frequency) electrical stimulation that produces sensory and motor responses (i.e., a tickling sensation and plantar flexion or fanning of all toes). The recommended course of treatment is an initial series of 12 weekly office-based treatments followed by an individualized maintenance treatment schedule.

Transvaginal radiofrequency bladder neck suspension, which has been investigated as a method of treatment for stress urinary incontinence, involves the use of radiofrequency (RF) energy to shrink and stabilize the endopelvic fascia. An incision is made through the vagina lateral to the urethra, exposing the endopelvic fascia. RF energy is then applied over the endopelvic fascia in a slow sweeping manner, resulting in blanching and shrinkage of the tissue. The procedure is similar in concept to thermal capsulorrhaphy, which has been used to treat shoulder instability.

Transurethral radiofrequency micro-remodeling, which has also been investigated as a method of treatment for stress urinary incontinence, involves the use of radiofrequency (RF) energy to remodel collagen in the submucosal tissue to increase tissue resistance. The device used in this type of treatment (e.g., Renessa®) applies controlled heat to tissue targets within the lower urinary tract, denaturing collagen at multiple treatment sites. A single-use transurethral RF probe is used to heat submucosal tissue in the lower urinary tract to collagen-remodeling temperatures, causing microscopic regions to denature without significant necrosis or small vessel thrombosis.

Note: Sacral nerve stimulation is addressed in a separate medical policy (IV-83)

Policy:

Periurethral Bulking Agents

Use of the following periurethral bulking agents may be considered **MEDICALLY NECESSARY** to treat stress urinary incontinence.

- Collagen implants (e.g., Contigen Bard collagen implants)
- Carbon-coated spheres (e.g., Durasphere)
- Calcium hydroxylapatite (e.g., Coaptite®)
- Polydimethylsiloxane (e.g., Macroplastique®)

Use of these periurethral bulking agents as treatment for any other type of urinary incontinence is considered **INVESTIGATIVE.**

Use of autologous cellular therapy (e.g., myoblasts, fibroblasts, muscle-derived stem cells, or adipose-derive stem cells), autologous fat, and autologous ear chondrocytes is considered **INVESTIGATIVE**.

Use of any other periurethral bulking agents for urinary incontinence is considered **INVESTIGATIVE**.

Pelvic Floor Electrical Stimulation

Use of pelvic floor electrical stimulation (pelvic TENS) may be considered **MEDICALLY NECESSARY** as treatment for stress and/or urge incontinence in patients who have undergone a documented trial of pelvic muscle exercises for a period of at least six (6) months with no significant improvement in incontinence.

Personal Use Ultrasound Devices

Use of a portable personal use ultrasound device to non-invasively measure bladder volume (e.g., BladderManager®) is considered **MEDICALLY NECESSARY only** for spinal cord-injury patients with autonomic dysreflexia. All other uses are considered **NOT MEDICALLY NECESSARY**.

Botulinum Toxin Therapy

Botulinum toxin may be considered **MEDICALLY NECESSARY** for incontinence related detrusor overreactivity and incontinence of neurogenic origin (i.e., spinal cord injury, multiple sclerosis) that is inadequately controlled with anticholinergic therapy.

Magnetic Stimulation

Use of magnetic stimulation of the pelvic floor muscles [Extracorporeal Magnetic Innervation (ExMI™), NeoControl® Pelvic Floor System] as treatment for urinary incontinence is considered **INVESTIGATIVE** due to lack of clinical evidence indicating its impact on improved health outcomes.

Percutaneous Tibial Nerve Stimulation (PTNS)

Percutaneous tibial nerve stimulation may be considered **MEDICALLY NECESSARY** for treatment of urinary dysfunction (i.e., incontinence, urgency frequency, and non-obstructive urinary retention) in patients who meet all the following criteria:

- Absence of neurologic disease associated with detrusor hyperreflexia, and
- Absence of outlet obstruction, and
- Symptoms have resulted in significant disability (e.g., the frequency and/or severity of leakages are limiting the patient's ability to work or participate in activities outside the home) and
- Conservative forms of treatment have been tried for at least one year and have failed

The use of percutaneous tibial nerve stimulation for any other indication is considered **INVESTIGATIVE.**

Transvaginal Radiofrequency Bladder Neck Suspension
Use of transvaginal radiofrequency bladder neck suspension for treatment of stress urinary incontinence is considered **INVESTIGATIVE** due to a lack of published evidence supporting its impact on improved health outcomes.

Transurethral Radiofrequency Micro-Remodeling
Use of transurethral radiofrequency micro-remodeling (e.g., Renessa) for treatment of stress urinary incontinence is considered **INVESTIGATIVE** due to a lack of published evidence supporting its impact on improved health outcomes.

Medically Unsupervised Treatments or Supplies
The following medically unsupervised treatments or supplies are considered **SELF-HELP** and **INELIGIBLE** for reimbursement: videotapes, books, biofeedback devices (Perrymeter, Perineometer), and any supplies related to the modalities listed above when they are not used as part of a supervised program.

Coverage: **Pre-Certification/Pre-Authorization: Yes, ONLY for Percutaneous Tibial Nerve Stimulation (PTNS).**

However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding: *The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

CPT:
51715 Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck

53860 Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence

53899 Unlisted procedure, urinary system

64566 Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

90901 Biofeedback training by any modality

90911 Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry

HCPCS:

E0740 Incontinence treatment system, pelvic floor stimulator, monitor, sensor, and/or trainer

E0746 Electromyography (EMG), biofeedback device

E1399 Durable medical equipment, miscellaneous

J0585 Injection, onabotulinumtoxinA, 1 unit

J0586 Injection, abobotulinumtoxinA, 5 units

J0587 Injection, rimabotulinumtoxinB, 100 units

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

ICD-9 Procedure:

59.72 Injection of implant into urethra and/or bladder neck

Deleted Codes: 0193T

Policy History:

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Medical Policy
Subcommittee Review:
Reviewed August 11, 1999
Reviewed December 13, 2000
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Cross Reference:
Botulinum Toxin, II-16
Sacral Nerve Stimulation for Pelvic Floor Dysfunction, IV-83
Durable Medical Equipment, VII-07
Electrotherapy / Electrotherapeutic Devices, VII-25