

Medical and Behavioral Health Policy

Section: Allied Health, Medicine

Policy Number: II-50

Effective Date: 01/20/2014

Blue Cross and Blue Shield of Minnesota medical policies do not imply that members should not receive specific services based on the recommendation of their provider. These policies govern coverage and not clinical practice. Providers are responsible for medical advice and treatment of patients. Members with specific health care needs should consult an appropriate health care professional.

TREATMENTS FOR URINARY DYSFUNCTION

Description: This policy addresses the following treatments for 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.

Definitions: **Magnetic stimulation (e.g., Extracorporeal Magnetic Innervation [ExMI™], NeoControl® Pelvic Floor System):** 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.

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.

Percutaneous tibial nerve stimulation (PTNS) (e.g., Urgent® PC Neuromodulation System): 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 involves insertion of a fine-needle electrode above the ankle into the posterior tibial nerve followed by the application of low-voltage electrical stimulation.

Periurethral bulking agents (e.g., collagen implants, Durasphere®, Coaptite®, Macroplastique®): Substances that are injected periurethrally to increase tissue bulk as a treatment of stress incontinence.

Personal use ultrasound device (e.g., BladderManager®): Monitors bladder fullness for individuals who must perform intermittent catheterization to enable catheterization to be done on the basis of bladder volume rather than on a timed schedule.

Transurethral radiofrequency micro-remodeling (e.g., **Renessa®**): Involves the use of radiofrequency (RF) energy to remodel collagen in the submucosal tissue to increase tissue resistance. This treatment is intended to apply controlled heat to tissue targets within the lower urinary tract, denaturing collagen at multiple treatment sites.

Transvaginal radiofrequency bladder neck suspension: Involves the use of radiofrequency (RF) energy to shrink and stabilize the endopelvic fascia.

Policy:

I. Botulinum Toxin Therapy

Botulinum toxin may be considered **MEDICALLY NECESSARY** for incontinence due to detrusor over activity, incontinence of neurogenic origin (e.g., spinal cord injury, multiple sclerosis), or overactive bladder in adults who have had an inadequate response to or are intolerant of an anticholinergic medication.

II. 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.

III. Pelvic Floor Electrical Stimulation

Use of pelvic floor electrical stimulation (i.e., 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.

IV. Percutaneous Tibial Nerve Stimulation (PTNS)

- A. 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:
1. Absence of neurologic disease associated with detrusor hyperreflexia; AND
 2. Absence of outlet obstruction; AND
 3. 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

4. Conservative forms of treatment have been tried for at least one year and have failed.
- B. The use of percutaneous tibial nerve stimulation for any other indication is considered **INVESTIGATIVE**.

V. Periurethral Bulking Agents

- A. Use of the following periurethral bulking agents may be considered **MEDICALLY NECESSARY** to treat stress urinary incontinence:
 1. Collagen implants (e.g., Contigen Bard collagen implants);
 2. Carbon-coated spheres (e.g., Durasphere);
 3. Calcium hydroxylapatite (e.g., Coaptite®);
 4. Polydimethylsiloxane (e.g., Macroplastique®);
- B. Use of these periurethral bulking agents as treatment for any other type of urinary incontinence is considered **INVESTIGATIVE**.
- C. Use of autologous cellular therapy (e.g., myoblasts, fibroblasts, muscle-derived stem cells, or adipose-derived stem cells), autologous fat, and autologous ear chondrocytes is considered **INVESTIGATIVE**.
- D. Use of any other periurethral bulking agents for urinary incontinence is considered **INVESTIGATIVE**.

VI. Personal Use Ultrasound Devices

- A. Use of a portable personal use ultrasound device to non-invasively measure bladder volume (e.g., BladderManager®) may be considered **MEDICALLY NECESSARY only** for spinal cord-injury patients with autonomic dysreflexia.
- B. All other uses are considered **INVESTIGATIVE**.

VII. 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.

VIII. 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.

Coverage:

Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan

description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims 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

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

HCPCS:

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

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

ICD-10 Procedure:

3E0K3GC Introduction of Other Therapeutic Substance into Genitourinary Tract, Percutaneous Approach

Deleted Codes: 0193T

**Policy
History:**

Developed November 13, 1996

Most recent history:

Revised November 10, 2010

Reviewed November 9, 2011

Revised November 14, 2012

Revised November 13, 2013

Cross

Botulinum Toxin, II-16

Reference:

Electrotherapy / Electrotherapeutic Devices, VII-25

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