curative

TITLE:	URINARY INCONTINENCE POLICY
POLICY #:	MM-PNP-060
VERSION #:	01
DEPARTMENT:	MEDICAL MANAGEMENT
ORIGINAL EFFECTIVE DATE:	4/12/2024
CURRENT REVISION DATE:	N/A

1. PURPOSE

This policy will be used to inform the medical necessity decisions related to authorization requests for urinary incontinence.

2. SCOPE

Medical UM Department

3. DEFINITIONS

N/A

4. RESPONSIBILITIES

Medical UM Department

5. POLICY

Medical Necessity

- Curative considers multi-channel urodynamic studies medically necessary when the patient has both symptoms and physical findings of urinary incontinence/voiding dysfunctions (such as stress incontinence, overactive bladder, lower urinary tract symptoms) and there is consideration by the provider to perform invasive, potentially morbid, or irreversible treatments after conservative management has been tried and failed.
- Curative considers the following urinary incontinence interventions medically necessary when criteria are met:

Artificial Urinary Sphincter

- Curative considers the implantation of an artificial urinary sphincter (AUS) medically necessary for the treatment of urinary incontinence (UI) due to intrinsic urethral sphincter deficiency (IUSD) for patients with any of the following indications:
    - Children with intractable UI due to IUSD who are refractory to behavioral or pharmacological therapies and are unsuitable candidates for other types of surgical procedures for correction of UI; *or*
    - Patients who are 6 or more months post-prostatectomy have had no improvement in the severity of UI despite trials of behavioral and pharmacological therapies; *or*
    - Patients with epispadias-exstrophy in whom bladder neck reconstruction has failed; *or*

- Women with intractable UI who have failed behavioral, pharmacological, and other surgical treatments.

Curative considers the artificial urinary sphincter experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established.

Periurethral Injections of Bulking Agents

Curative considers periurethral injections of bulking agents that are cleared by the Food and Drug Administration (FDA) for UI (e.g., Bulkamid (polyacrylamide hydrogel), Coaptite [calcium hydroxylapatite], Contigen [glutaraldehyde cross-linked collagen], Durasphere [carbon-coated spheres/beads], Macroplastique [polydimethylsiloxane], Uryx [ethylene vinyl alcohol copolymer]) medically necessary for the management of patients with UI resulting from intrinsic sphincter deficiency that is refractory to conservative management (e.g., Kegel exercises, biofeedback, electrical stimulation, and/or pharmacotherapies).

Patients whose incontinence does not improve after 3 treatments with bulking agents are considered treatment failures and are not likely to respond to this therapy. In such cases, further treatment with bulking agents is not considered medically necessary.

Curative considers injection of periurethral bulking agents for UI experimental and investigational for neurogenic bladder and all other indications.

Implantable Sacral Nerve Stimulators (e.g., Axonics and InterStim)

Curative considers permanent implantation (Stage 2) of FDA-approved implantable sacral nerve stimulators (e.g., Axonics and InterStim) medically necessary for the treatment of urge UI or symptoms of urge-frequency when all the following criteria are met:

- The Patients experienced urge UI 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 patient's ability to participate in daily activities); *and*
- Pharmacotherapies (i.e., at least 2 different anti-cholinergic drugs or an anticholinergic and a beta-3 adrenergic receptor agonist (mirabegron)) as well as behavioral treatments (e.g., pelvic floor exercise, biofeedback, timed voids, and fluid management) have failed; *and*
- Test stimulation (Stage 1) provides at least 50 % decrease in symptoms.
- The test stimulation (Stage 1) of the device is considered medically necessary for patients who meet selection criteria 1 and 2 above.
- Curative also considers permanent implantation (Stage 2) of a sacral nerve stimulator medically necessary for the treatment of nonobstructive urinary retention when *all* the following criteria are met:

- The Patients have experienced urinary retention for at least 6 months and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the patient's ability to participate in daily activities); *and*
- Pharmacotherapies (e.g., alpha blockers and antibiotics for urinary tract infections) as well as intermittent catheterization have failed or are not well-tolerated; *and*
- A test stimulation (Stage 1) of the device has provided at least 50 % decrease in residual urine volume.

Curative considers test stimulation (Stage 1) of the right and left sides (where leads are placed bilaterally; and each side are assessed sequentially during a single visit) medically necessary for patients who meet selection criteria 1 and 2 above for treatment of urgent incontinence and non-obstructive urinary retention. No more than 6 total test stimulations (Stage 1) are considered medically necessary. Curative considers permanent placement (Stage 2) of bilateral sacral nerve stimulation experimental and investigational for the treatment of UI and non-obstructive urinary retention because the effectiveness of this approach has not been established.

Curative considers removal of an implantable sacral nerve stimulator medically necessary even where the initial implantation of the implantable sacral nerve stimulator was not indicated.

Curative considers the use of implantable sacral nerve stimulator experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established.

According to the product labeling, implantable sacral nerve stimulator is contraindicated and has no proven value for individuals who have not demonstrated an appropriate response to test stimulation (Stage 1) or are unable to operate the neurostimulator.

Exclusions

Implantable sacral nerve stimulators have no proven value for individuals with mechanical obstruction such as benign prostatic hypertrophy, or urethral stricture; persons with stress incontinence; and individuals with neurological disease origins, such as multiple sclerosis or diabetes with peripheral nerve involvement. Implantable sacral nerve stimulator has not shown to be effective for urinary retention due to these causes.

Vaginal Cones

Curative considers weighted vaginal cones (vaginal weights) medically necessary DME when they are used in combination with a structured pelvic floor muscle exercise (Kegel's exercise) program for the treatment of simple (pure) stress UI.

Curative considers vaginal cones experimental and investigational for other indications because their effectiveness for indications other than the ones listed above has not been established.

Pessary (Bladder Neck Support Prosthesis)

Curative considers a pessary, a plastic device that fits into the vagina to help support the uterus and bladder, medically necessary DME for the treatment of women with stress or mixed UI, and for the treatment of pelvic organ (uterine) prolapse.

Curative considers a pessary experimental and investigational for other indications because its effectiveness for indications other than the ones listed above has not been established.

Tension-Free Vaginal Tape Procedure

Curative considers the tension-free vaginal tape (TVT) procedure medically necessary for the treatment of stress UI when women with intractable UI have failed behavioral and pharmacological treatments.

Curative considers the TVT procedure experimental and investigational for other indications (except for the treatment of pelvic organ prolapse complicated by stress UI - see Organ Prolapse: Selected Procedures) because its effectiveness for indications other than the one listed above has not been established.

Transobturator Tape Procedure

Curative considers the transobturator tape (TOT) procedure medically necessary for the treatment of stress UI when women with intractable stress UI have failed behavioral and pharmacological treatments.

Curative considers the TOT procedure experimental and investigational for urge urinary incontinence and other indications because its effectiveness for indications other than the one listed above has not been established.

Colposuspension and Sling Procedures

Curative considers colposuspension and conventional suburethral sling procedures (e.g., the Solyx single-incision sling) medically necessary for persons with stress UI that is refractory to conservative management (e.g., pelvic floor muscle training, electrical stimulation, and biofeedback).

Curative considers the colposuspension and suburethral sling procedures experimental and investigational for other indications because their effectiveness for indications other than the one listed above has not been established.

Biofeedback

For biofeedback for UI, see Biofeedback.

Percutaneous Tibial Nerve Stimulation

Curative considers percutaneous tibial nerve stimulation (PTNS) (e.g., the eCoin Peripheral Neurostimulator System, and Urgent PC Neuromodulation System, Uroplasty, Inc., Minneapolis, MN) medically necessary for the treatment of patients with urge UI or urge-frequency when they meet the first 2 criteria listed for Implantable Sacral Nerve Stimulators (e.g., Axonics and InterStim) (policy section I.B.3a and I.B.3b for the treatment of urge urinary incontinence or symptoms of urge-frequency). In general, 12 treatments (once weekly) with PTNS are needed for symptom relief. If the patient fails to improve after 12 PTNS treatments, continued treatment is considered not medically necessary. If the patient improves after 12 PTNS treatments, continued monthly treatments are considered medically necessary as long as the patient's symptoms remain improved.

Curative considers percutaneous tibial nerve stimulation experimental and investigational when criteria are not met.

Transurethral Radiofrequency Therapy (Renessa Procedure)

Curative considers transurethral radiofrequency therapy (Renessa procedure) medically necessary for the treatment of stress UI in non-pregnant women who are either not able or not willing to undergo surgery for their condition.

Urethral Inserts

Curative considers urethral inserts medically necessary for the treatment of female stress UI.

Curative considers urethral inserts experimental and investigational for other indications because their effectiveness for indications other than the one listed above has not been established.

Cunningham Clamp

Curative considers the Cunningham clamp medically necessary for the treatment of post-prostatectomy urinary incontinence in men with stress incontinence and good bladder storage function.

Intravaginal Electrical Stimulation

Curative considers intravaginal electrical stimulation of the pelvic floor medically necessary for women with stress, urgency, or mixed urinary incontinence.

Experimental and Investigational

Curative considers the following UI interventions experimental and investigational because the effectiveness of the treatment has not been established:

- The Neocontrol™ System, which uses extracorporeal magnetic innervation (ExMI)
- Radiofrequency micro-remodeling with the SURx System (paraurethral or transvaginal)
- Laser Therapy: The Genityte Procedure (laser therapy) and FemiLift (CO2 laser)
- Pudendal nerve stimulation
- *Adjustable* retropubic suburethral sling in the treatment of stress urinary incontinence
- Autologous myoblast transplantation
- Autologous muscle-derived cell therapy
- Collagen porcine dermis mesh
- Stem cell therapy (including mesenchymal stem/stromal cells)
- Magnetically controlled end urethral artificial urinary sphincter
- Transcutaneous electrical nerve stimulation (TENS) in the treatment of overactive bladder
- Transperineal implantation of permanent adjustable balloon continence device (e.g., ACT, ProACT Therapy System, Uromedica, Inc.)
- Vibratory perineal stimulation
- Bariatric surgery as a treatment of urinary incontinence in persons who would otherwise not meet medical necessity criteria for obesity surgery in Obesity Surgery
- The Adjustable Transobturator Male System for the treatment of stress urinary incontinence (SUI)
- Magnetic stimulation for the treatment of women with SUI
- Moxibustion for the treatment of post-stroke UI
- Dynamometry for quantification of pelvic floor muscle strength in female urinary incontinence
- Genetic testing for stress urinary incontinence
- Periurethral injections of bulking agents for *any* of the following circumstances:
- Patients undergoing or planning to undergo desensitization injections to meat products; *or*
- Patients with acute condition involving cystitis, urethritis, or infection; *or*
- Patients with severe allergies manifested by a history of anaphylaxis, or history or presence of multiple severe allergies; *or*
- Previous pelvic radiation therapy; *or*
- Unstable or non compliant bladder

Policy Limitations and Exclusions

Pelvic Muscle Trainers

Note: Curative does not cover the Athena pelvic muscle trainer, Gyneflex, Kegelmaster, Leva Pelvic Floor Trainer, or similar devices for the treatment of UI because these devices are considered exercise machines, and they do not meet Curative definition of covered durable medical equipment (DME). Most Curative plans exclude coverage of exercise devices. Please check the benefit plan descriptions for details. In addition, such exercise devices do not meet the Curative definition of covered DME because they are not primarily medical in nature and/or are normally of use to patients who do not have an illness or injury.

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

7.1. All Medical UM associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal, and equitable remedies may apply.

9. DOCUMENTATION

N/A

10. REFERENCE DOCUMENTS AND MATERIALS

10.1. Related Policies

- Biofeedback
- Obesity Surgery
- Organ Prolapse: Selected Procedures

11. COLLABORATING DEPARTMENTS

N/A

12. DOCUMENT CONTROL

APPROVED BY:		
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(Printed Name)	**(Date)**	**(Signature)**

REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

Any applicable attachments, resources or other materials should be included as appendices in this section. Label each appendix as follows:

Appendix A:

N/A