Sentara Health Plans

Medicaid

Urinary Incontinence Treatments, Medical 174

Table of Content

Effective Date	9/2008
Next Review Date	10/2025
Coverage Policy	Medical 174
Version	7

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses the medical necessity for various urinary incontinence treatments.

Description & Definitions:

Urinary incontinence is the involuntary loss of urine. There are different treatments available to reduce leakage.

Criteria:

Urinary incontinence treatments are considered medically necessary for **ALL** of the following:

- Failure of behavioral modification training for individuals who can understand and comply with these regimens (e.g. bladder training, prompted voiding, pelvic muscleexercise)
- The primary causes of incontinence have been ruled out or adequately treated, including **ALL** of the following:
  - Detrusor instability
  - Urge incontinence
  - Urinary frequency
  - Fistula
  - Urethral ectopy
  - Bladder calculi
  - Urethral diverticula
  - Overflow incontinence
- Treatment includes **1 or more** of the following:
  - Periurethral bulking agents include carbon-coated zirconium oxide particles (i.e., Durasphere), calcium hydroxylapatite [CaHA] particles (i.e., Coaptite), and silicone elastomer/polydimethylsiloxane (i.e., Macroplastique-as indicated by the FDA) with **ALL** of the following:

- Demonstration of stress incontinence (e.g., Marshall test, cystography, urodynamic testing)

        - Negative postvoid residual urine test < 75ml for an adult
    - Weighted vaginal cones (vaginal weights) when they are used in combination with a structured pelvic floor muscle exercise (e.g. Kegel's exercise) program for thetreatment of simple (pure) stress urinary incontinence
    - Biofeedback for individuals who carry the benefit
    - Urethral inserts for adult with stress incontinence when the beneficiary or caregiver can perform the procedure
    - Endoscopic injection of bulking agents (specifically FDA approved for vesicoureteral reflux such as e.g., Deflux®) as an alternative to surgery for clinically severevesicoureteral reflux Grade II-IV in children one year of age or older
    - Artificial urinary sphincter implantation as a treatment of urinary stress incontinence with evidence of **1 or more** of the following:
        - Primary implantation, as indicated by **ALL** of the following:
            - Moderate to severe stress incontinence or total urinary incontinence
            - No detrusor overactivity, or detrusor overactivity has been successfully treated (eg, with anticholinergic drugs)
            - Individual is able to manipulate pump
        - Reimplantation for device failure, erosion, or after removal of infected device
    - Percutaneous tibial nerve stimulation (PTNS) may be indicated when **ALL** of the following
        - Failure or contraindication to medication (ie, antimuscarinic) therapy
        - Overactive bladder syndrome
        - Symptoms not due to underlying neurologic condition (eg, multiple sclerosis, Parkinson disease, spinal cord injury)
    - Transurethral Radiofrequency Therapy (Renessa Procedure) for the treatment of stress urinary incontinence in non-pregnant individuals who are either not able or notwilling to undergo surgery for their condition

Urinary incontinence treatments is considered **not medically necessary** for uses other than those listed in the clinical criteria, to include but not limited to:

- Genityte Laser Procedure
- Transperineal periurethral balloon continence device (i.e., ProACT)
- Leva Pelvic Health System

Coding:

Medically necessary with criteria:

Coding	Description
51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck
52327	Cystourethroscopy (including ureteral catheterization); with subureteric injection of implant material
53445	Insertion of inflatable urethral/bladder neck sphincter, including placement of 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, a 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
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

90901	Biofeedback training by any modality
90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the Individual
90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the Individual (List separately in addition to code for primary procedure)
A4336	Incontinence supply, urethral insert, any type, each
A4356	External urethral clamp or compression device (not to be used for catheter clamp), each
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

Considered Not Medically Necessary:

Coding	Description
53451	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy
53452	Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy
53453	Transperineal periurethral balloon continence device; removal, each balloon
53454	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume
97026	Application of a modality to 1 or more areas; infrared
S9002	Intravaginal motion sensor system, provides biofeedback for pelvic floor muscle rehabilitation device

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2024: October – Added HCPCS S9002 to not covered section
- 2023: August
- 2022: October
- 2021: December
- 2020: December
- 2019: October
- 2016: January
- 2015: March, August, September
- 2014: October
- 2013: January, March, April, May, July
- 2012: April, November
- 2010: March, April, August
- 2009: January, April

Reviewed Dates:

- 2019: March

- 2017: December
- 2014: April
- 2011: April
- 2010: July

Effective Date:

- August 2008

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

Code of Federal Regulations. Search for Urinary Incontinence. Retrieved 9.20.2024. https://www.govinfo.gov/app/search/%7B%22query%22%3A%22urinary%20incontinence%22%2C%22offset%22%3A0%2C%22facets%22%3A%7B%22accodenav%22%3A%5B%22CFR%22%5D%7D%2C%22filterOrder%22%3A%5B%22accodenav%22%5D%7D

U.S. Food and Drug Administration. Guidance for Industry and Food and Drug Administration Staff Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence Document issued on: March 8, 2011. Retrieved 9.20.24. https://www.fda.gov/media/71054/download

Hayes. A symplr Company. Clinical Research Response, May 16, 2024, Revi (BlueWind Medical) for the Treatment of Urinary Incontinence. Retrieved 9.20.24. https://evidence.hayesinc.com/report/crr.revi5866

Hayes. A symplr Company. Emerging Technology Report, Nov 2, 2023, Nuvella System (Neuspera Medical Inc.) for Urinary Urge Incontinence. Retrieved 9.20.24. https://evidence.hayesinc.com/report/pg.nuvella

Hayes. A symplr Company. Evidence Analysis Research Brief, Aug 2, 2023, NexWave (Zynex Medical) for Treatment of Overactive Bladder and Urge Incontinence. Retrieved 9.20.24. https://evidence.hayesinc.com/report/earb.nexwave5674

Hayes. A symplr Company. Evidence Analysis Research Brief, Jul 31, 2023, Pelvic Floor Electrical Stimulation for the Treatment of Urinary Incontinence. Retrieved 9.20.24. https://evidence.hayesinc.com/report/earb.pelv0001

Hayes. A symplr Company. Evolving Evidence Review. Jan 13, 2023. Ieva Pelvic Health System (Renovia Inc.) for Treatment of Urinary Incontinence. Retrieved 9.20.24. https://evidence.hayesinc.com/report/eer.ieva5372

Centers for Medicare and Medicaid Assistance Services. Biofeedback Therapy for the Treatment of Urinary Incontinence. 30.1.1. 7.1.2001. Retrieved 9.20.24. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=42

Centers for Medicare and Medicaid Assistance Services. Sacral Nerve Stimulation For Urinary Incontinence. 230.18. Retrieved 9.20.24. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=249

Centers for Medicare and Medicaid Assistance Services. Local Coverage Determination (LCD). Sacral Nerve Stimulation for the Treatment of Urinary and Fecal Incontinence. L39543. 11.5.2023. Retrieved 9.20.24. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39543&ver=5

Centers for Medicare and Medicaid Assistance Services. Incontinence Control Devices. 230.10. 10.7.1996. Retrieved 9.20.24. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=241

Centers for Medicare and Medicaid Assistance Services. Non- Implantable Pelvic Floor Electrical Stimulator. 230.8. 6.19.2006. Retrieved 9.20.24. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=231

Centers for Medicare and Medicaid Assistance Services. Local Coverage Determination (LCD). Urological Supplies. LCD L33803. 1.1.24, Retrieved 9.20.24. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33803

MCG. Informed Care Strategies. 28th Edition. Urethral Bulking Agent Injections. ACG: A-0268 (AC). Retrieved 9.20.24. https://careweb.careguidelines.com/ed28/index.html

MCG. Informed Care Strategies. 28th Edition. Biofeedback. ACG: A-0330 (AC). Retrieved 9.20.24. https://careweb.careguidelines.com/ed28/index.html

MCG. Informed Care Strategies. 28th Edition. Artificial Urinary Sphincter. ACG: A-0267 (AC). Retrieved 9.20.24. https://careweb.careguidelines.com/ed28/index.html

Commonwealth of Virginia. Department of Medical Assistance Services. DMAS.gov. Provider Manual search. Retrieved 9.20.24. https://vamedicaid.dmas.virginia.gov/pdf_chapter/practitioner#gsc.tab=0&gsc.q=incontinence&gsc.sort=

Commonwealth of Virginia. Department of Medical Assistance Services. DMAS.gov. Procedure Fee Files & CPT Codes. Retrieved 9.20.2024. https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/#searchCPT

National Comprehensive Cancer Network. Retrieved 9.20.2024. https://www.nccn.org/search-result?indexCatalogue=nccn-search-index&searchQuery=urinary%20incontinence

Carelon Clinical Guidelines. Retrieved 9.20.2024. https://guidelines.carelonmedicalbenefitsmanagement.com/physical-occupational-and-speech-therapies-2024-04-14/?highlight=urinary+incontinence&hilite=urinary+incontinence

American College of Obstetrics and Gynecologists. Urinary Incontinence in Women. Practice Bulletin. Number 155. Reaffirmed 2022. Retrieved 9.20.2024. https://journals.lww.com/greenjournal/fulltext/2015/11000/practice_bulletin_no__155__urinary_incontinence_in.51.aspx

PubMed. National Library of Medicine. Lugo, T., Leslie, S. W., Mikes, B. A., & Riggs, J. (2024). Stress Urinary Incontinence. In StatPearls. Retrieved 9.20.2024. https://www.ncbi.nlm.nih.gov/books/NBK539769/

Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

Keywords:

SHP Urinary Incontinence Treatments, SHP Medical130, behavioral modification training, bladder training, prompted voiding, pelvic muscle exercise, Detrusor instability, Urge incontinence, Urinary frequency, Fistula, Urethral ectopy, Bladder calculi, Urethral diverticula, Overflow incontinence, Periurethral bulking agents, carbon-coated zirconium oxide particles, Durasphere, calcium hydroxylapatite particles, Coaptite, silicone elastomer/polydimethylsiloxane, Macroplastique, Marshall test, cystography, urodynamic testing, postvoid residual urine test, weighted vaginal cones, pessary, Urethral inserts , biofeedback, Endoscopic injection of bulking agents, pelvic floor rehabilitation, peripheral nerve evaluation, sacral nerve stimulation, Permanent sacral nerve stimulator, Interstim, Deflux®, Artificial urinary sphincter implantation, Pelvic Floor Rehabilitation, Electrical Nerve Stimulation, Transcutaneous, PTNS, Electrical Stimulation, Behavioral therapy, bladder training, pelvic muscle exercises, cones, pessaries,Pharmacotherapy, anticholinergics, Serotonin–norepinephrine reuptake inhibitors, SNRI's, Condom catheter, Percutaneous Tibial Nerve stimulation, Intermittent catheterization, Indwelling catheter, transurethral, suprapubic, pulse generator, percutaneous peripheral nerve stimulation, sling procedure, Transurethral Radiofrequency Therapy, Renessa Procedure, Pelvic floor electrical stimulators, Mechanical incontinence control devices, hydraulic incontinence control devices, collagen implant