Urinary Dysfunction Treatments

MEDICAL POLICY NUMBER: 180

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to OHA's prioritized list for the following coverage guidelines:

Artificial Urinary Sphincter: Guideline Note 193, Line 457
Posterior Tibial Nerve Stimulation: Guideline Note 235
Injectable Bulking Agents: Excluded Services Guideline E1 and Excluded Services Guideline E2
Sacral Nerve Stimulation: Guideline Note 129, Line 529

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Notes:

- For Botox treatment for urinary incontinence, please see separate Pharmacy policy: Botulinum Toxin.
- This policy does not apply to the following treatments for urinary incontinence, which may be considered medically necessary:
    - Biofeedback
    - Colposuspension and sling procedures
    - Pessary
    - Vesicouretal reflux (e.g. Deflux)

Artificial Urinary Sphincter

I. Implantation of an artificial urinary sphincter may be considered **medically necessary** for patients with urinary stress incontinence who meet **either** of the following criteria (A. or B.):
   A. Six or more months post-prostatectomy with symptoms refractory to behavioral and pharmacological therapies; **or**
   B. Meets **both** of the following criteria (a.-b.)
      a. Patient's symptoms limit activities of daily living; **and**

   b. Failure, intolerance or contraindication to conservative management (medication, physical therapy, bladder training, etc.)

II. Implantation of an artificial urinary sphincter is considered **not medically necessary** when criterion I. above is not met.

Injectable Bulking Agents

III. FDA-approved injectable bulking agents (e.g. Coaptite, Durasphere, Macroplastique) may be considered **medically necessary** for patients with urinary stress incontinence who meet **all** of the following criteria:

   A. Patient's symptoms limit activities of daily living; **and**
   B. Failure, intolerance, or contraindication to conservative medical management; **and**
   C. Patient lacks the following contraindications (1. and 2.):
      1. Acute urogenital tract inflammation or infection; **and**
      2. Fragile urethral mucosal lining (e.g. post-radiation therapy, post-surgery to the bladder neck.)

IV. Injectable bulking agents are considered **not medically necessary** when criterion III. above is not met.

Percutaneous Tibial Nerve Stimulation (PTNS)

Initial Treatment

V. Percutaneous tibial nerve stimulation administered once weekly for up to 12 weeks may be considered **medically necessary** for patients with urinary urge incontinence who meet **all** of the following criteria (A.- C.):

   A. Patient's symptoms limit activities of daily living; **and**
   B. Failure, intolerance or contraindication to conservative medical management; **and**
   C. Patient has failed a trial of **two** different classes of medications (e.g. antimuscarinic/anticholinergics and beta-3 adrenoceptor agonists), unless contraindicated.

VI. Percutaneous tibial nerve stimulation is considered **not medically necessary** when criterion V. above is not met.

Additional Treatments

VII. Subsequent treatments of percutaneous tibial nerve stimulation may be considered **medically necessary** and will be allowed at a frequency of 1 every month for a maximum of 2 years provided there is documented improvement in symptoms (e.g. voiding diary). The 2-year time period begins with the initiation of PTNS treatment.

VIII. More than 12 treatments of percutaneous tibial nerve stimulation is considered **not medically necessary** when there is no documented improvement in symptoms (e.g. voiding diary).

Removal of Percutaneous Tibial Nerve Stimulation (PTNS)

IX. Removal of an percutaneous tibial nerve stimulator may be considered **medically necessary** if it has been thoroughly evaluated and found to be no longer functional and was appropriately placed for medical necessity.

Sacral Nerve Stimulation

Trial Period

X. A trial period of sacral nerve stimulation with a temporarily implanted lead may be considered **medically necessary** for patients with urinary urge incontinence or non-obstructive urinary retention when **all** of the following criteria are met (A.- D.):

A. Patient's symptoms limit activities of daily living; **and**
B. Failure, intolerance, or contraindication to conservative medical management or behavioral treatments (e.g. pelvic floor exercises or intermittent catheterizations for non-obstructive urinary retention); **and**
C. Patient has failed a trial of two different classes of medications (e.g. antimuscarinic/anticholinergics and beta-3 adrenoceptor agonists), unless contraindicated; **and**
D. Incontinence is not related to a spinal cord injury or progressive, systemic neurologic condition.

XI. A trial period of sacral nerve stimulation is considered **not medically necessary** when criterion IX. above is not met.

Permanent Implantation

XII. Permanent implantation of a sacral nerve stimulator may be considered **medically necessary** if the trial period demonstrates at least a 50% documented improvement in symptoms over a minimum trial period of 48 hours (e.g. voiding diary).

XIII. Permanent implantation of a sacral nerve stimulator is considered **not medically necessary** when criterion XI. above is not met.

Device Removal/Replacement

XIV. Device removal or replacement may be considered **medically necessary** if the device has been thoroughly evaluated and found to be no longer functional and was appropriately placed for medical necessity.

Non-Covered Treatments

XV. The following treatments of urinary incontinence are considered **not medically necessary** (A.-F.):

A. Implanted Adjustable Continence Therapy (e.g., ProAct Therapy System)
B. Implantable tibial nerve stimulator (e.g., eCOIN Peripheral Neurostimulator System)
C. Percutaneous tibial nerve stimulator (e.g., ZIDA Wearable Neuromodulation System)
D. Intraurethral valve-pump (e.g., InFlow™ Intraurethral Valve-Pump from Vesiflo, Inc.)
E. Pelvic Floor Electrical Stimulation
F. Transurethral Radiofrequency Therapy (Renessa Procedure)
G. Transcutaneous tibial nerve stimulator (e.g., Vivally System)
H. Vaginal Cones
I. External female catheters (e.g., PureWick Urine Collection System)
J. Endovaginal cryogen-cooled, monopolar radiofrequency remodeling
K. Flyte® System Controller

Link to Evidence Summary

POLICY CROSS REFERENCES

- Neuromuscular Drugs Botulinum Toxin (Pharmacy Policy)

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

Urinary Incontinence

Urinary incontinence refers to the involuntary loss of urine. It has a high degree of prevalence in the older population and is a significant contributor to healthcare costs, disability and reduced quality of life.

Urinary incontinence is categorized as stress incontinence (SUI), urge incontinence (UUI) or mixed incontinence (MUI) (a combination of stress and urge incontinence). Stress urinary incontinence is the predominant type of urinary incontinence in women, and is the complaint of involuntary leakage of urine during exertion, sneezing or coughing. Urge urinary incontinence is the predominant type of urinary incontinence in men, and describes the sudden urge to urinate and the involuntary loss of urine.

Nearly all people with incontinence will benefit from conservative treatment including physical therapy, increasing fitness and weight loss. Those with an element of urge incontinence may also benefit from treatment with a medication aimed at reducing detrusor muscle over activity. Stress incontinence may be effectively treated in some women with a pessary.

Treatments of Urinary Incontinence

Artificial Urinary Sphincter

The artificial urinary sphincter is an implanted device consisting of three interconnected silicone components: a cuff, a balloon reservoir and a pump, each of which is attached to a length of silicone tubing. The cuff is filled with saline fluid and compresses the urethra to prevent leakage. When ready to urinate, the patient squeezes the pump (implanted in the scrotum or upper thigh), which pulls fluid from the cuff into the pressure-regulating balloon, thereby releases compression on the urethra and allowing urination. After several minutes, saline fluid automatically returns from the pressure regulating balloon to the cuff, thereby squeezing the urethra closed once more.

Injectable Bulking Agents

Implanted in the urethral wall, these implants reduce the inner diameter of the urethra, and provide focal pressure on the proximal urethra, thereby increasing urethral resistance and improving patients' continence.[1] Materials used in bulking agents may include: glutaraldehyde cross-linked bovine collagen (i.e. Contigen®); carbon-coated zirconium oxide particles (i.e. Durasphere®); calcium hydroxylapatite particles (i.e. Coaptite®); and silicone elastomer/polydimethylsiloxane (Macroplastique®).

Percutaneous Tibial Nerve Stimulation

Percutaneous tibial nerve stimulation delivers an electrical current to the sacral nerve plexus via an electrode place in a superficial branch of the posterior tibial nerve in the ankle. The low-voltage pulse hypothetically stimulates and strengthens pelvic floor function such that incontinence improves.

Sacral Nerve Stimulation

Sacral nerve stimulation is the surgical application of a mild electrical pulse to a sacral nerve, which influences the functioning of the bladder, bowel, anal sphincter, and the pelvic floor muscles. The implanted electrode connects to an external pulse generator, which provides continuous stimulation to the pelvic floor musculature, thereby improving pelvic floor function.

Pelvic Floor Electrical Stimulation

Pelvic floor electrical stimulation refers to a class of non-implanted devices that deliver electrical stimulation indirectly to the pelvic floor and pudendal nerve. Stimulation contracts the pelvic floor, thereby purportedly strengthening pelvic floor muscles, increasing urethral pressure and preventing leakage during an abrupt increase in intra-abdominal pressure.[2]

Transurethral Radiofrequency Therapy (Renessa Procedure)

Transurethral radiofrequency uses non-ablative levels of radiofrequency energy to shrink and stabilize the endopelvic fascia, thereby purportedly improving support for the urethra and bladder neck and improving continence.

Vaginal Cones

Vaginal weight training is a behavioral therapy that employs weights during Kegel or pelvic floor exercises to strengthen pelvic floor muscles and improve continence. Weighted cones are inserted into the vagina and the patient contracts the pelvic floor to prevent them from slipping out.[3]

Implanted Adjustable Continence Therapy (e.g. ProAct Therapy System)

ProAct is an implantable device consisting of two volume-adjustable silicone balloons that are surgically placed in either the bladder neck or at the apex of the prostatic remnant. These balloons are connected to bi-lumen tubing with a subcutaneous injection port at the end. The balloons purportedly increase the amount of pressure required to urinate, thereby guarding against unintentional leakage brought about by sneezing or coughing. Device ports are used to perform periodic surgical balloon volume adjustments.[4]

Intraurethral valve-pump (e.g., inFlow™ Intraurethral Valve-Pump)

The inFlow™ Intraurethral Valve-Pump is the first device of this type. It is a temporary, replaceable urethral valve-pump for use in adult women with impaired detrusor contractility (IDC). The device consists of multiple components, including a miniature valve-pump that is inserted into the urethra and left in place. The valve-pump is operated via remote control, allowing the bladder to empty when activated and blocking urinary flow after bladder emptying. A physician performs the initial device insertion; after training, device insertion and removal can be performed by the patient or a caregiver. The inserted component of the device must be replaced at least once every 29 days.
Endovaginal cryogen-cooled, monopolar radiofrequency treatment

The Viveve System, previously used to treat sexual dysfunction, has recently been piloted to treat stress urinary incontinence symptoms.[5] This device delivers monopolar radiofrequency with cryogen cooling to protect the upper epithelial layers of the mucosa while also enabling energy to reach the deeper tissues layers, resulting in volumetric heating of important connective tissue

Implantable tibial nerve stimulator

The eCoin Peripheral Neurostimulator System is an implantable posterior tibial nerve stimulation (PTNS) device for the treatment of urgency urinary incontinence (UUI). The eCoin is less invasive than sacral nerve stimulation (SNS) and is intended to fill a need for additional treatment options for UUI due to overactive bladder (OAB) in patients who are intolerant of or refractory to conservative therapies.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

The following are examples of devices that have received FDA clearance (not all inclusive):

- **Artificial Urinary Sphincter**: The Artificial Urinary Sphincter[6]
- **Bulking Agents**: Contigen,[7] Coaptite,[8] Durasphere,[9] Macroplastique,[10] URYX[11]
- **Percutaneous Tibial Nerve Stimulation**: Urgent PC Neuromodulation System[12]
- **Sacral Nerve Stimulation**: Axonics Sacral Nruomodulation System[13], Medtronic Interstim® Sacral Nerve Stimulation™ System[14]
- **Pelvic Floor Electrical Stimulation**: NeoControl® Pelvic Floor Therapy System;[15] MyoTrac Infiniti;[16] ApexM;[17] In Tone®MV.[18]
- **Adjustable Continence Therapy:** ProACT™ Adjustable Continence Therapy for Men[19]
- **Intraurethral valve-pump:** InFlow™ Intraurethral Valve-Pump (Vesiflo, Inc.)
- **Implantable Tibial Nerve Stimulator:** eCoin Peripheral Neurostimulator, Valencia Technologies Corporation[20]

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding various treatments for urinary incontinence. Below is a summary of the available evidence identified through June 2022.

Artificial Urinary Sphincter

Non-Neurogenic Severe Stress Urinary Incontinence

In 2020 Barakat and colleagues completed a systematic review and meta-analysis of clinical and functional outcomes of artificial urinary sphincters in women with stress urinary incontinence.[21] Fifteen studies, totaling 964 individuals, were included within the review, utilizing the Newcastle-Ottawa score for determining evidence quality. Complete continence was achieved at a mean rate of 79.6% and significant improvement was achieved in 15%. The authors stated that artificial urinary sphincter is an effective treatment option after failure of first-line therapy for the treatment of severe stress urinary incontinence. However, additional studies are needed with larger patient populations.

In 2018, Reus and colleagues evaluated the safety and efficacy of an artificial urinary sphincter (AMS 800) for the treatment of severe stress urinary incontinence (SUI) in non-neurogenic women.[22] Independent investigators systematically searched the literature through February 2018, identified eligible studies, assessed study quality, extracted data and pooled reported results. In total, 12 studies were included for review (n=886), none of which were prospective or randomized. Median follow-up across studies was 69 months. The outcome of "complete continence" was evaluated in all 12 studies – the proportion varied between 42% and 86%. Anticipated serious adverse event rates ranged from 2% to 54% across 6 studies. The level of evidence for both performance and safety outcomes was very low.

Limitations included reviewed studies' retrospective and non-randomized design, small sample sizes, inadequate follow-up, heterogeneous outcome measures and heterogeneous patient selection criteria. Investigators concluded that evidence supporting the use of an AUS remains insufficient and that large, prospective and randomized trials were to establish the safety and validity of AUS.

Neurogenic Severe Stress Urinary Incontinence

In 2016, Farag and colleagues conducted a systematic review evaluating the efficacy of various surgical treatments, including artificial urinary sphincters (AUS), for the treatment of neurogenic stress urinary incontinence.[23] Surgical outcomes of success, failure, and reoperation were calculated. Across 8 studies included for review (n=399), AUS patients experienced significantly better outcomes than patients receiving urethral bulking agents (77 ± 15% vs. 27 ± 20%, p=0.002). However, the reoperation rate for AUS patients was higher than patients receiving either urethral slings or bulking agents. Limitations include a lack of prospective and randomized studies and heterogeneity of outcome measures and patient selection criteria. Investigators called for additional, high-quality studies to establish the safety and efficacy of AUS.

Injectable Bulking Agents

In 2022, Braga and colleagues completed a systematic review and meta-analysis on urethral bulking agents for the treatment of recurrent stress urinary incontinence following a failure of a mid-urethral sling.[24] Eleven publications were selected for inclusion, which were a mix of retrospective and prospective studies worldwide with one multicenter inclusion. The Newcastle-Ottawa scale was utilized to evaluate risk of bias. Five studies presented a low risk of bias and all the other studies presented a moderate risk of bias. The main reason for bias was the failure to include the selection of controls. Improvement rate of continence ranged from 64-85% compared with the pooled failure and re-operation rate of 32%. The authors concluded the results were promising for intervention after mid-urethral sling failure, but recommended future studies include shared and common protocols.

In 2018 and 2017, Hayes conducted two reviews of abstracts evaluating the safety and efficacy of various injectable bulking agents (i.e. Macroplastique, Coaptite, and Durasphere EXP) for the treatment of stress urinary incontinence.[1,25] Searching the literature through June 2018, Hayes identified a combined total of 19 abstracts many of which were manufacturer-funded and reported mixed results. Both reports determined that evidence was insufficient to assess any injectable bulking agent. Hayes called for large, high-quality trials with long-term follow-up to establish the treatment's safety and efficacy.

In 2018, Capobianco and colleagues conducted a systematic review and meta-analysis evaluating the safety and efficacy of a bulking agent (Urolastic) for the treatment of stress urinary incontinence.[26] Investigators systematically searched the literature through January 2018, identified eligible studies, assessed study quality, extracted data and pooled reported results. In total, 5 studies were included for full-text review (n =276). Follow-up among included studies ranged from 6 to 24-months. Investigators reported that the pooled proportion of secondary injections in treated patients was 20% (95% CI: 15%–24%; I^2:0%). Subjective improvement was only assed in 2 of 5 studies and was measured by different means. Four of five studies evaluated treatment success, with a pooled proportion of 57% (95% CI: 38%–75%; I^2: 82.3%). The pooled proportion of complication rates across all studies was 36% (95% CI: 17%-57%; I^2: 91.3%). Limitations across included studies include heterogeneous outcomes, inadequate follow-up, small sample sizes, and the lack of comparator groups receiving alternative bulking agents. Investigators called for additional, larger studies to establish the efficacy of Urolastic.

In 2017, Cochrane conducted a systematic review evaluating injectable bulking agents in the treatment of urinary incontinence in women.[27] Investigators systematically searched the literature through November 2010, identified eligible studies, assessed study quality and extracted data. In total, 35 reports from 14 trials were included for review (n=2,004). The trials were assessed to be of moderate quality.
One trial compared bulking agents to conservative treatment and found bulking agents superior with respect to continence grade (RR 0.70, 95% CI: 0.52 to 0.94) and quality of life (mean difference: 0.54, 95% CI 0.16 to 0.92). Two trials compared injection to surgical management and reported superior outcomes in the surgical group (RR 4.77, 95% CI 1.96 to 11.64; and RR 1.69, 95% CI 1.02 to 2.79), although this difference was only significant in one of the two trials. Eight trials compared bulking agents of different kinds. All agents were shown to be effective comparable to collagen. Noting that meta-analyses remain impossible due to a lack of standardized assessment measures, investigators concluded that the evidence base was insufficient to suggest that bulking agents can relieve stress incontinence in women. Investigators called for both comparative randomized trials involving a placebo or conservative treatment arm, as well as long-term comparative trials with specific surgical procedures to determine long-term safety and efficacy of bulking agents as a standard first-line treatment for urinary incontinence.

In 2017, ECRI conducted an evidence review evaluating the efficacy of the Macroplastique urethral bulking agent for the treatment of stress urinary incontinence (SUI) in adult women.[28] ECRI searched the literature through September 2017, reviewing the abstracts of six studies and full text of one study that evaluated 3,886 patients (i.e. 3 systematic reviews (43 studies; n=3,637); 2 RCTs (n=90) and 2 non-randomized controlled trials (n=159)).

Among patients receiving Macroplastique, the three systematic reviews reported improved subjective success rates, improved symptom rates, and a positive association between the number of re-injections and improved long-term SUI outcomes. Investigators from each systematic review concluded that bulking agents should be considered a safe and effective treatment option for patients who are both unsuitable for more invasive procedures and willing to accept the need for potential repeat injections. Two RCTs (comparing Macroplastique to pelvic floor exercises and pubovaginal slings) reported significant improvements in Macroplastique at follow-up ranging from 12 to 62 months.

Limitations in this review include the lack of full text evaluation and the lack of quality assessment by ECRI. Most studies included for review lacked comparator groups receiving either alternative bulking agents or surgical treatments. Nonetheless, Macroplastique appeared effective and well-tolerated in patients across studies. ECRI concluded that comparative evidence was insufficient to demonstrate Macroplastique's superiority to other bulking agents or SUI treatments. ECRI called for additional RCTs evaluating these treatments to confirm the results of the 2 small RCTs conducted to date.

Three earlier systematic reviews evaluating bulking agents reported mixed results in included studies.[23,29,30] Two of these reviews called for additional RCTs that evaluated standardized clinical outcomes to establish the safety and efficacy of bulking agents.[23,29]

Percutaneous Tibial Nerve Stimulation

In 2022, Hayes published an updated comparative effectiveness review evaluating PTNS for the treatment of non-neurogenic overactive bladder syndrome.[31] Having searched the literature through September 2018, 12 RCTs were included for review, all of which evaluated adults who had not responded to standard medical therapies. Sample sizes ranged from 30 to 220 patients and follow-up varied from 4 weeks to 40 weeks.
Collectively, evidence from RCTs suggested that PTNS patients experienced superior symptom resolution to patients receiving sham PTNS. PTNS was also at least as effective as standard care with standard antimuscarinic (AM) drug therapy. As an adjunct to AM drug therapy, PTNS was generally superior to either therapy alone for improving moderate-to-severe symptoms and disease-specific quality of life (QOL). Mixed evidence suggested that PTNS is less effective for certain urinary outcomes compared with transvaginal electrical stimulation and intra-detrusor injection of onabotulinum toxin A (ID Btx-A). Compared to sham therapy, PTNS patients consistently improved the overall response, urinary symptoms and urinary-related quality of life (QOL). Compared to AM drug therapy alone, PTNS patients experienced a superior overall response. However, evidence of benefit for urge urinary incontinence was mixed, and no significant differences between groups were reported for urinary symptoms and QOL. Compared to either PTNS alone or AM drug therapy alone, patients receiving PTNS plus AM drug therapy reported equivalent or superior urinary and QOL outcomes. One study reported that transvaginal stimulation alone was more effective than PTNS alone for voiding frequency and urinary QOL. Another study suggested that ID Btx-A may be more effective than PTNS alone. However, give the paucity of data for both comparators, effectiveness could not be determined.

Hayes assessed as “moderate,” the quality of evidence comparing PTNS to either sham PTNS or AM drug therapy. Conversely, the quality of evidence regarding PTNS as an adjunct therapy for the treatment of overactive bladder was assessed as “low,” and, for PTNS versus other comparators, as “very low.” Five of the 12 RCTs were conducted in low-middle income treatment settings, which may further limit results’ generalizability.

Despite these limitations, Hayes assigned a “B” rating for use of PTNS alone relative to standard drug therapy (some proven benefit); a “C” rating for use of PTNS plus standard AM drug therapy (potential but unproven benefit); and “D2” ratings” for use of PTNS alone (insufficient evidence). Hayes concluded that while PTNS may be an effective treatment for adults with symptoms refractory to conservative care, additional RCTs were needed to define patient selection criteria and establish the long-term efficacy of PTNS.

In 2018, Tutolo and colleagues conducted a systematic review evaluating sacral nerve stimulation and percutaneous tibial nerve stimulation in patients with non-neurogenic lower urinary tract dysfunction who had failed to respond to more conservative therapies. [32] Independent investigators systematically searched the literature through June 2017, identified eligible studies, assessed study quality and extracted data.

In total, 9 studies were identified, including 4 RCTs evaluating the efficacy of PTNS (n=388). Follow-up among studies averaged 3 months. One RCT compared PTNS to tolterodine and reported subjective cure or symptom improvements in 79.5% of PTNS patients compared to 54.8% of tolterodine patients ($p = 0.01$), although objective assessments did not demonstrate significant difference. Two additional RCTs, comparing PTNS to placebos, reported moderate to marked improvement among 54.5% of PTNS patients versus 20.9% in the control group ($p < 0.001$). Voiding diaries showed statistically significantly better results in PTNS patients. The overall success/improvement rate in PTNS varied between 54% and 79%. PTNS patients also experienced fewer side effects than those patients receiving sacral nerve stimulation. Investigators concluded that PTNS can be considered a valid alternative therapy for overactive bladder syndrome.

Across included studies, limitations include the lack of standardization of outcome measures, small sample sizes, and inadequate follow-up. Investigators concluded that PTNS appeared to improve symptoms in the short-term, with fewer side effects than patients receiving SNS. Nonetheless, investigators called for additional studies with long-term follow up to confirm validity of results reported to date.

Sacral Nerve Stimulation

Systematic Reviews

- In 2021 ECRI completed a clinical evidence assessment on sacral nerve stimulation for treating urinary incontinence (InterStim Implantable).[33] Two systematic reviews (14 studies with n=1,239; 7 studies with n=704), one multicenter RCT (n=386), two prospective multicenter before-and-after studies (n=214; n=272), and two retrospective case series (n=1,474; n=565) addressing patient-oriented outcomes were assessed. The analysis suggested that InterStim is safe and relieves urinary incontinence and urinary frequency symptoms in most patients. The single RCT reviewed suggests that InterStim works as well as botulinum toxin (Botox) injections for reducing urinary incontinence symptoms. Evidence limitations discuss the RCT is at medium risk of bias, while the before-and-after studies are at high risk of bias because of lack of parallel controls and because participating centers followed their own implantation protocols. Case series are also at high risk of bias due to retrospective design, single-center focus, and lack of controls. Evidence bar rating of somewhat favorable.

- In 2010 (updated 2014; archived 2015), Hayes evaluated the safety and efficacy of sacral nerve stimulation (SNS) for the treatment of urinary voiding dysfunction.[34] Hayes searched the literature through May 2014 for studies reporting clinical outcomes for at least 50 patients. In total, 18 studies were included for review (1 RCT, 10 prospective controlled or uncontrolled case series, and 7 retrospective case series). The findings of 4 systematic reviews were also assessed. Sample sizes in included studies ranged from 51 to 581 patients. The primary outcome measured was incontinence symptom relief as measured and recorded by patients in daily voiding diaries.

  Studies indicated that SNS may reduce symptoms of urge incontinence and improve quality of life in patients with urge incontinence, non-obstructive urinary retention, and urinary urgency-frequency syndrome. In the pivotal RCT on which FDA approval for the Interstim device is based, 183 patients (83%) with urgency-frequency symptoms reported increased voiding volumes with the same or reduced degree of frequency after 6 months of treatment. At 12 months, 81% of patients had reached normal voiding frequency. Among patients for whom data were available, these improvements were sustained for up to five years. SNS patients also reported significant improvements in quality of life compared to control group patients. Limitations of this RCT included the lack of placebo control and imprecisely defined guidelines for patient eligibility. The results of uncontrolled studies were generally positive with several studies reporting greater than 60% clinical efficacy of SNS at ≥ 5-year follow-up. Evidence was insufficient to demonstrate the efficacy of SNSS for the treatment of both neurogenic voiding dysfunction and mixed urinary incontinence due to a limited number of studies. No serious adverse events were reported as of 2014. Definitive patient selection criteria had also not yet been established.

Hayes concluded that SNS may be an appropriate treatment option for patients with documented urge incontinence, non-obstructive urinary retention, or urinary urgency-frequency syndrome who failed to respond to more conservative medical therapies. Hayes ultimately assigned a "B" rating (some proven benefit) for use of SNS as a last-resort therapy before consideration of bladder surgery in patients with urinary urge incontinence, non-obstructive urinary retention, or urgency-frequency syndrome who experience > 50% incontinence symptom relief during a trial of percutaneous SNS; a "C" rating for SNS in patients with neurogenic voiding dysfunction (potential but unproven benefit); and "D" ratings (insufficient evidence) for SNS in patients with mixed urinary incontinence and other incontinence conditions, or as a first line therapy.

- In 2024, Hayes published a health technology assessment for sacral nerve stimulation for treatment of non-obstructive urinary retention.[35] Hayes included 6 studies in its investigation, 1 RCT, 1 pretest-posttest study, 1 repeated measure study, and 3 case series. The RCT found that SNS provided statistically significant increases in mean number of spontaneous voids per day and mean volume per day compared to continued conservative therapy. Hayes gave a C rating for treatment of adults with nonneurogenic non-obstructive urinary retention (NOUR) with sacral nerve stimulation (SNS).

  They concluded, "This Rating reflects an overall low-quality body of evidence that suggests that SNS provides medium- to long-term relief of nonneurogenic NOUR symptoms in most patients, with ≥ 50% response during the initial testing phase of SNS treatment. No major safety issues were identified, although a lack of treatment response or device-related complications may result in the need for subsequent surgical intervention."[35]

Randomized Controlled Trials

Since the publication of the Hayes review discussed above, several RCTs have evaluated the efficacy of SNS in treating urinary incontinence. One study reported significantly superior improvements in symptom severity and quality among 120 SNS patients compared to patients receiving tolterodine.[36] Another study (n=70) reported therapeutic success at 61% of SNS patients compared to 42% in the standard treatment group (p <0.02), as well as significantly superior QOL scores.[37] A third study reported a therapeutic response rate of 85% among SNS patients at 12-month follow-up, although data from the control group of patients receiving only standard therapy was not included.[38] A fourth RCT reported clinically equivalent improvements in urge incontinence reductions per day between 189 patients treated with SNS and a control arm of 192 patients treated with onabotulinumtoxinA.[39]

Pelvic Floor Electrical Stimulation

In 2020 (archived March 2021), Hayes updated a health technology evaluating the safety and efficacy of pelvic floor stimulation (PFS) for the treatment of both stress urinary incontinence (SUI) and urge urinary incontinence (UUI).[2] Hayes systematically searched the literature, identified eligible studies, assessed quality and extracted data. For women with SUI, sample sizes ranged from 45 to 200 patients (n=895); for women with UUI, sample sizes ranged from 40 to 148 (n=308); for men with SUI post radical retropubic prostatectomy (RRP), sample sizes ranged from 56 to 139 patients (n=258).

In total, 12 RCTs evaluated the effectiveness of PFS in women with urinary incontinence, and 3 RCTs evaluated the effectiveness of PFS in men with UI. Outcomes of interest included symptom relief, durability of continence, and improved quality of life (QOL) as measured by bladder diaries and patient specific questionnaires. Follow-up ranged from 9 months to 8 years. Results indicated that PFS improved UI symptoms in women, although results were mixed and not always significant when treatment was compared to sham stimulation, no active treatment or another active treatment (usually pelvic floor muscle training). In men, limited data suggested that PFS combined with pelvic floor muscle training improves symptoms. No major adverse events were reported in any of the reviewed studies. The following is a summary of the RCT's evaluated by Hayes:

Women with Stress Urinary Incontinence

PFS vs. Sham Stimulation

Three RCTs compared PFS to sham stimulation and reported conflicting results. Two of the three studies reported unverified improvements in urinary leakage and frequency symptoms compared to the control group. None of the studies found consistent improvements in quality of life outcomes, although 1 study reported improvements when assessed by a visual analog scale.

PFS vs. No Active Treatment

Compared with patients receiving no active treatment, 2 of 3 RCTs reported a significant reduction in number of episodes of urine leakage, amount of urine leakage, and improvements in quality of life, posttreatment urodynamic testing and social activity.

PFS vs. Pelvic Floor Muscle Training

Compared to patients receiving PFS, 2 RCTs suggested that patients receiving pelvic floor muscle training (PFMT) experienced superior outcomes. One RCT reported significant reduction in urine leakage in the control group compared to PFS patients ($p = 0.02$). Another RCT reported superior subjective results for PMFT over PFES, with similar quality of life outcomes between the two groups.

PFS plus PFMT vs. PMFT Alone

Two RCTs reported no significant difference between treatment groups for any outcome (i.e. urinary leakage, frequency, quality of life and patient satisfaction.)

PFS plus PFMT vs. PFS Alone

One RCT found significant improvements within both treatment groups. No significant differences were reported regarding urinary frequency, incontinence, nocturia or patient satisfaction.

<u>Women with Urge Urinary Incontinence</u>

PFS vs. Sham Stimulation

Two RCTs provided conflicting results. One study found significant improvements among PFS patients in urinary frequency and patient-reported outcomes, as well fewer patients with detrusor instability posttreatment. A second RCT found no significant reduction in urinary leakage, percentage of patients with UUI posttreatment, or percentage of satisfied patients between groups.

PFS compared with Pelvic Muscle Exercise

One RCT reported no significant difference is in resolution of urinary urgency, urodynamic outcomes, or other urinary symptoms. PFS patients reported significant improvements in quality of life outcomes compared with pelvic muscle exercise patients.

<u>Men with Stress Urinary Incontinence</u>

PFS plus PFMT vs. PMFT Alone

Two RCTs found no significant differences between groups in number of continent patients, or in urine leakage posttreatment. A third study reported significant improvements in continence, at 3- and 6-month follow-up, but not at 12-months. PFS plus PFMT patient experiences reduced time to continence.

Hayes judged the overall quality of evidence as “low.” Limitations included heterogeneity in patient populations, treatment protocols and comparator groups, as well as heterogeneity among studies in how and when outcomes were assessed. Definitive patient selection criteria remain unestablished. Hayes assigned a “C” rating (potential but unproven benefit) for PFS as a treatment for women with both urge urinary incontinence and stress urinary incontinence not caused by a neurological disease, stating that evidence was inconsistent and low-quality despite several positive results. Hayes assigned a “D2” rating (insufficient evidence) for PFS as a treatment for men with both urge- and stress urinary incontinence. Hayes concluded that additional, well-designed RCTs were necessary to definitively establish efficacy, but that PFS may be viable for patients with symptoms refractory to more conservative treatments.

Transurethral Radiofrequency Therapy (Renessa Procedure)

In 2015, a Cochrane systematic review evaluated transurethral radiofrequency collagen denaturation (TRT) to treat individuals with urinary incontinence.[40] Independent investigators searched the literature through December 2014, identified eligible studies, assessed study quality and extracted data. Only one trial was identified: a manufacturer-funded, sham-controlled randomized trial of 173 women (mean age: 50 years). Two-thirds of patients (n=115) were randomly assigned either TRT or a sham surgery using a non-functioning catheter. Follow-up was 12 months. The study did not demonstrate improved quality of life. The risk of other adverse events (pain/dysuria (RR: 5.73, 95% CI 0.75 to 43.70); new detrusor over-activity (RR 1.36, 95% CI 0.63 to 2.93); and urinary tract infection (RR: 0.95, 95% CI 0.24 to 3.86) could not be established given the small size of the trial. Evidence was insufficient to determine the association between TRT and rate of urinary retention, hematuria and hesitancy compared with sham treatment. Evidence was insufficient assess whether the procedure causes adverse events. No evidence was found for comparison with any other method of treatment for UI. Investigators concluded that evidence is insufficient to show whether TRT improves patient-reported symptoms of UI or quality of life.

Vaginal Cones

In 2013, Cochrane conducted a systematic review evaluating the safety and efficacy of weighted vaginal cones for the treatment for urinary incontinence.[3] Independent investigators searched the literature through March 2013, identified eligible studies (i.e. randomized or quasi-randomized controlled trials comparing weighted vaginal cones with alternative treatments or no treatment), assessed study quality and extracted data. In total, 23 trials were included for review (n= 1806; 717 received cones).

Results across studies reported that cones were superior to no active treatment, although there was little evidence demonstrating a difference between cones plus pelvic floor muscle training (PFMT) compared to either cones alone, or PFMT alone. There was also little evidence of difference for a subjective cure between cones and PFMT (RR: 1.01, 95% CI 0.91 to 1.13), or between cones and electrostimulation (RR: 1.26, 95% CI 0.85 to 1.87).

Limitations among reviewed studies included small sample sizes, heterogeneous outcome measures, and high attrition rates. Investigators concluded that while the efficacy of weighted vaginal cones may be comparable to PFMT and electrostimulation, larger, high-quality trials that measure comparable and relevant outcomes were necessary to more definitively establish efficacy.

Implanted Adjustable Continence Therapy (e.g. ProAct Therapy System)

In 2021 ECRI updated their clinical evidence assessment on ProACT adjustable Continence Therapy for male stress urinary incontinence.[41] The literature search from January 2016 through September 2021 yielded one systematic review with meta-analysis (Larson et al.) reporting on 19 studies and 1,264 patients. This review reporting on urinary incontinence symptoms, quality of life, and adverse events with a mean 3.6 year follow-up. The review found that 81.9% of patients reported being either “dry” or “improved” (improved defined as a > 50% in daily pad use with a baseline average of 4 pads/day). The meta-analysis also found that Incontinence Quality of Life Scale scores improved by a mean of 67% at three-year follow-up. There was a mean 22.2% three-year revision rate for ProACT, largely driven by leakage, migration, or urinary tract erosion. Evidence limitations include significant heterogeneity and no studies compared ProACT with full-cuff artificial urinary sphincter. Studies included in the meta-analysis were rated as low to good quality (10 good quality, 7 moderate quality, 2 low quality). ECRI recommends additional multicenter controlled trials that directly compare ProACT with other treatment options for stress urinary incontinence. ECRI evidence bar rating was inconclusive.

Non-randomized Studies

Two non-randomized studies published results evaluating ProACT's safety and efficacy among 294 patients.[42,43] One study, reporting results at median 9 year follow-up, found a success rate among 82.6% of patients (n=112 out of 160). Both studies reported improvements from baseline in number of pads used, and quality of life measures. Investigators concluded that study results demonstrated the safety and efficacy of ProACT, despite high reported revision rates. Limitations include the studies' lack of randomization, the lack of comparator groups and manufacturer funding for one study.[42]

Intraurethral valve-pump (e.g., InFlow™ Intraurethral Valve-Pump)

A search of PubMed regarding intraurethral valve-pump identified two reports. In 1998, Pannek reported a case of acute urinary retention was caused by a mucus clot obstructing the pump.[44]

In 2005, Chen and colleagues reported that only 77 of 273 patients completed the treatment phase of a trial comparing the safety, effectiveness and patient satisfaction of an intraurethral valve-pump catheter versus the current standard of care (clean intermittent catheterization (CIC) for females with hypocontractile or acontractile bladder.[45] The reasons for the large early withdrawal of subjects (169/273) were mainly related to initial discomfort and leakage. There was no information available about other adverse effects such as UTI, bladder inflammation, genitourinary pain, hematuria, bladder spasms, asymptomatic bacteriuria, vulvar, vaginal and urethral disorders.

Endovaginal cryogen-cooled, monopolar radiofrequency treatment

A single, interim report by Allan and colleagues in 2020 was identified, evaluating the six-month preliminary data on a prospective, investigator-initiated feasibility study.[5] An initial review of bladder voiding diaries suggests that subjects are having fewer urine leakage episodes per day as well as 68.8-69.2% of subjects have experienced a >50% reduction in pad weight in 1-hour pad-weight test.

Implantable tibial nerve stimulator

In 2023, Hayes published an evolving evidence review on eCoin Peripheral Neurostimulator System (Valencia Technologies Corp.) for urgency urinary incontinence.[46] The review studies suggests minimal support for using the eCoin Peripheral Neurostimulator System for urgency urinary incontinence (UUI). Hayes reports, "Findings from 3 poor-quality single-arm studies (in 4 publications) suggest that the eCoin Peripheral Neurostimulator System may significantly reduce the number of daily urgency urinary incontinence (UUI) episodes and improve patient quality of life up to 12 months of follow-up. None of the studies compared eCoin with placebo, sham, or active controls. Device-related adverse events were typically mild to moderate, with overall rates ranging from 19.5% to 21.7% across 2 studies. No systematic reviews or guidelines addressing eCoin were identified." This level of support reflects:

- All 3 eligible studies were of poor quality and did not have comparison groups with placebo, sham, or active treatments.

- Studies consistently reported significant reductions in the number of daily UUI episodes, substantial response rates, and improvements in quality of life (QOL).
- Mild to moderate adverse events were commonly reported, but serious adverse events occurred infrequently.
- There was substantial patient population overlap in 2 of 3 studies.

CLINICAL PRACTICE GUIDELINES

Artificial Urinary Sphincter (AUS)

In 2019, the National Institute for Health and Care Excellence (NICE) recommended the use of artificial urinary sphincter for the management of stress urinary incontinence in women only if previous surgery is failed. Life-long follow-up was also recommended for patients treated with an AUS.[47]

In 2017, the American Urological Association (AUA) stated that artificial urinary sphincters may be used in patients with a non-mobile urethra.[48] In the 2024 guidelines for incontinence after prostrate treatment, AUA also had the following guideline statement, "Clinicians should discuss the option of artificial urinary sphincter with patients who are experiencing mild to severe stress urinary incontinence after prostate treatment. (Strong Recommendation; Evidence Level: Grade B)."[49]

Injectable Bulking Agents

In 2019, the National Institute for Health and Care Excellence (NICE) recommended the use of bulking agents for patients if other surgery is "unsuitable for, or unacceptable to, the woman." The guidance also advised that women should be "fully advised of the risks, the lack of evidence for long-term effectiveness and adverse events, and that other surgical procedures may be more effective."[47]

In 2017, the American Urological Association (AUA) issued a strong recommendation for bulking agents in the treatment of stress urinary incontinence, especially for patients who wish to avoid more invasive surgery or who experience insufficient improvement following a previous anti-incontinence procedure.[48] In 2015 (reaffirmed 2018), the American College of Obstetricians and Gynecologists issued a level B recommendation (limited or inconsistent evidence) for bulking agents, stating that injections "may be appropriate if surgery has failed to achieve adequate symptom reduction, if symptoms recur after surgery, in women with symptoms who do not have urethral mobility, or in older women with comorbidities who cannot tolerate anesthesia or more invasive surgery."[50]

Percutaneous Tibial Nerve Stimulation (PTNS)

In 2019, NICE recommended for the use of PTNS only if "there has been a multidisciplinary team review, and non-surgical management including overactive bladder medicine treatment has not worked adequately and the woman does not want botulinum toxin or percutaneous sacral nerve stimulation."[47]

In 2019, the American Urological Association Education and Research, Inc. and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction published an evidence-based guideline amendment as followup to the Agency for Healthcare Research and Quality (AHRQ) Evidence Report/Technology Assessment Number 187 titled Treatment of Overactive Bladder in Women (2009).[51] For patients with moderate to severe symptoms, PTNS and SNS were included as treatment options depending on the patient's desire and willingness to engage in treatment beyond education, behavioral treatment, and pharmacologic management.

Sacral Nerve Stimulation

In 2019, NICE recommended for the use of sacral nerve stimulation after multi-disciplinary review only if the patients has not responded to conservative management and they are "not prepared to accept the risks of needing cathertisation associated with botulinum toxin type A.[47]

In 2015 (reaffirmed 2018), the American College of Obstetricians and Gynecologists stated that sacral nerve stimulation may be considered for patients who have failed other conservative measures.[50]

Pelvic Floor Electrical Stimulation

In 2015 (reaffirmed 2018), the American College of Obstetricians and Gynecologists stated that, while efficacy remains unclear, pelvic muscle exercises may be used with electrical stimulation.[50]
In 2019, NICE recommended against the routine use of electrical stimulation in treatment of women with overactive bladder. The guidance also recommended against the routine use of electrical stimulation in combination with pelvic floor muscle training, but recommended the combination for women who cannot actively contract pelvic floor muscles so as to aid motivation and adherence. [47]

EVIDENCE SUMMARY

For urinary dysfunction patients with symptoms refractory to conservative treatment, low-quality but consistent evidence supports the use of artificial urinary sphincters and injectable bulking agents. Several evidence-based, clinical practice guidelines also recommend their use. Clinical practice guidelines and recent systematic reviews also indicate that percutaneous tibial nerve stimulation and sacral nerve stimulation may similarly improve symptoms. Evidence does not support, however, the efficacy of transurethral radiofrequency therapy, muscle training with vaginal cones, muscle training with pelvic floor electrical stimulation, or implanted adjustable continence therapies. Systematic reviews evaluating these therapies note a lack of long-term evidence from high-quality trials, and call for additional, large and randomized studies with direct comparison to other urinary incontinence treatment options to establish treatments' safety and efficacy.

HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.
The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy

policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

BILLING GUIDELINES AND CODING

CODES*		
CPT	0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system for bladder dysfunction including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
	0588T	Revision or removal of percutaneously placed integrated single device neurostimulation system for bladder dysfunction including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
	0589T	Electronic analysis with simple programming of implanted integrated neurostimulation system for bladder dysfunction (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 1-3 parameters
	0590T	Electronic analysis with complex programming of implanted integrated neurostimulation system for bladder dysfunction (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 4 or more parameters
	0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement
	0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement
	0672T	Endovaginal cryogen-cooled, monopolar radiofrequency remodeling of the tissues surrounding the female bladder neck and proximal urethra for urinary incontinence
	0786T	Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed
	0787T	Revision or removal of neurostimulator electrode array, sacral, with integrated neurostimulator
	0788T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation,

		detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 1-3 parameters
	0789T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 4 or more parameters
	0816T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous
	0817T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial
	0818T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous
	0819T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subfascial
	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
	53444	Insertion of tandem cuff (dual cuff)
	53445	Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff
	53446	Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
	53447	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session
	53449	Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
	53451	Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance
	53452	Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance
	53453	Periurethral transperineal adjustable balloon continence device; removal, each balloon
	53454	Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume
	53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence

	64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
	64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
	64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
	64585	Revision or removal of peripheral neurostimulator electrode array
	64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
	64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
	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 patient
	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 patient (List separately in addition to code for primary procedure)
	97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
	97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
HCPCS	A4290	Sacral nerve stimulation test lead, each
	A4335	Incontinence supply; miscellaneous
	A4341	Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each
	A4342	Accessories for patient inserted indwelling intraurethral drainage device with valve, replacement only, each
	A4545	Supplies and accessories for external tibial nerve stimulator (e.g., socks, gel pads, electrodes, etc.), needed for one month
	A6590	External urinary catheters; disposable, with wicking material, for use with suction pump, per month
	A6591	External urinary catheter; non-disposable, for use with suction pump, per month
	E2001	Suction pump, home model, portable or stationary, electric, any type, for use with external urine and/or fecal management system
	E0715	Intravaginal device intended to strengthen pelvic floor muscles during kegel exercises
	E0716	Supplies and accessories for intravaginal device intended to strengthen pelvic floor muscles during kegel exercises
	E0737	Transcutaneous tibial nerve stimulator, controlled by phone application
	E0745	Neuromuscular stimulator, electronic shock unit
	C1767	Generator, neurostimulator (implantable), non-rechargeable
	C1778	Lead, neurostimulator (implantable)

	C1815	Prosthesis, urinary sphincter (implantable)
	C1816	Receiver and/or transmitter, neurostimulator (implantable)
	C1883	Adapter/extension, pacing lead or neurostimulator lead (implantable)
	C1897	Lead, neurostimulator test kit (implantable)
	E0736	Transcutaneous tibial nerve stimulator
	E0740	Non-implanted pelvic floor electrical stimulator, complete system
	~~K1006~~	**TERMED 12/31/2023** ~~Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system~~
	K1010	Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each
	K1011	Activation device for intraurethral drainage device with valve, replacement only, each
	K1012	Charger and base station for intraurethral activation device, replacement only
	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
	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each
	L8682	Implantable neurostimulator radiofrequency receiver
	L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
	L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
	L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
	L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
	L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
	L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only
	L9900	Orthotic and prosthetic supply, accessory and/or service component of another HCPCS "L" code.

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.

- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
3/2023	Interim update. Update to: indications for criteria, conservative measures.
4/2023	Q2 code set update
5/2023	Interim update. Added device removal criteria and added implantable tibial nerve stimulation to criterion XVI
10/2023	Annual update. Changed denial type from “investigational” to “not medically necessary.” Removed criterion III.C requiring urinary incontinence due to intrinsic sphincter deficiency for injectable bulking agents.
1/2024	Q1 2024 code set update.
4/2024	Q2 2024 code set update.
10/2024	Annual update. Added criteria for non-obstructive urinary retention. Policy title change. Q4 2024 code set update.