


<b>MEDICAL POLICY</b>	<b>Urinary Incontinence Treatments (All Lines of Business Except Medicare)</b>
<b>Effective Date: 8/1/2021</b>	Medical Policy Number: 180
 8/1/2021	Technology Assessment Committee Approved Date: 3/16 Medical Policy Committee Approved Date: 2/13; 4/14; 7/15; 4/17; 6/18; 5/19; 11/19; 06/2020; 10/2020; 4/2021; 7/2021
Medical Officer	Date

**See Policy CPT/HCPCS CODE section below for any prior authorization requirements**

**SCOPE:**

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

**APPLIES TO:**

All lines of business except Medicare

**BENEFIT APPLICATION**

Medicaid Members

*Oregon:* Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**POLICY CRITERIA**

Notes:

- For Botox treatment for urinary incontinence, please see separate Pharmacy policy: Botulinium Toxin.
- This policy does not apply to biofeedback for urinary incontinence which may be considered medically necessary.

**Artificial Urinary Sphincter**

I. Implantation of an artificial urinary sphincter may be considered **medically necessary and covered** for patients who meet **either** of the following criteria (A. or B.):

A. Urinary incontinence refractory to behavioral, pharmacological, and other surgical treatments; **or**

- B. Six or more months post-prostatectomy with symptoms refractory to behavioral and pharmacological therapies.
- II. Implantation of an artificial urinary sphincter is considered **investigational and is not covered** 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 and covered** for patients who meet **both** of the following criteria (A. and B.):
  - A. Urinary incontinence resulting from intrinsic sphincter deficiency that is refractory to conservative management; **and**
  - B. 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 **investigational and are not covered** when criterion III. above is not met.

#### **Percutaneous Tibial Nerve Stimulation**

##### *Initial Treatment*

- V. Percutaneous tibial nerve stimulation administered once weekly for up to 12 weeks may be considered **medically necessary and covered** for patients 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 **investigational and is not covered** when criterion V. above is not met.
- VII. More than 12 treatments of percutaneous tibial nerve stimulation is considered **investigational and is not covered** when there is no documented improvement in symptoms (e.g. voiding diary).

*Additional Treatments*

- VIII. More than 12 treatments of percutaneous tibial nerve stimulation may be considered **medically necessary and covered** when there is documented improvement in symptoms (e.g. voiding diary). Subsequent treatments will be allowed at a frequency of 1 every month for a maximum of 2 years. The 2 year time period begins with the initiation of PTNS treatment.

**Sacral Nerve Stimulation***Trial Period*

- IX. A trial period of sacral nerve stimulation with a temporarily implanted lead may be considered **medically necessary and covered** when **both** of the following criteria are met (A. and B.):
- A. Patient symptoms are refractory to conservative behavioral treatments (e.g. pelvic floor exercises); **and**
  - B. Incontinence is not related to a spinal cord injury or progressive, systemic neurologic condition.
- X. A trial period of sacral nerve stimulation is considered **investigational and is not covered** when criterion IX. above is not met.

*Permanent Implantation*

- XI. Permanent implantation of a sacral nerve stimulator may be considered **medically necessary and covered** if the trial period demonstrates a documented improvement in symptoms (e.g. voiding diary).
- XII. Permanent implantation of a sacral nerve stimulator is considered **investigational and is not covered** when criterion XI. above is not met.
- XIII. Removal or replacement of a scaral nerve stimulator is considered **not medically necessary and not covered** if the initial device remains functional.

**Non-Covered Treatments**

- XIV. Other treatments of urinary incontinence are considered **not medically necessary and are not covered**, including but not limited to, the following (A.-F.):
- A. Implanted Adjustable Continence Therapy (e.g. ProAct Therapy System)

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- B. Intraurethral valve-pump (e.g., InFlow™ Intraurethral Valve-Pump from Vesiflo, Inc.)
  - C. Pelvic Floor Electrical Stimulation
  - D. Transurethral Radiofrequency Therapy (Renessa Procedure)
  - E. Vaginal Cones
  - F. External female catheters (e.g. PureWick Urine Collection System)
- Link to [Policy Summary](#)

**CPT/HCPCS CODES**

All Lines of Business Except Medicare	
Prior Authorization Required	
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0588T	Revision or removal of integrated single device neurostimulation system 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 (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 (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
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

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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
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
A4290	Sacral nerve stimulation test lead, each
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)
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

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No Prior Authorization Required	
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
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
A4335	Incontinence supply; miscellaneous
E0745	Neuromuscular stimulator, electronic shock unit
Not Covered	
53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence
<del>C9746</del>	<del>TERMED 6/30/19 Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed</del>
0548T	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy
0549T	Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy
0550T	Transperineal periurethral balloon continence device; removal, each balloon
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement
E0740	Non-implanted pelvic floor electrical stimulator, complete system
K1006	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

## DESCRIPTION

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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.<sup>1</sup> 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 placed 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*

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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.<sup>2</sup>

*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.<sup>3</sup>

*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.<sup>4</sup>

*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.

**REVIEW OF EVIDENCE**



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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 2021.

Artificial Urinary Sphincter

*Non-Neurogenic Severe Stress Urinary Incontinence*

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.<sup>5</sup> 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.<sup>6</sup> 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 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.<sup>1,7</sup> 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.<sup>8</sup> 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<sup>2</sup>:0%). Subjective improvement was only assessed 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<sup>2</sup>: 82.3%). The pooled proportion of complication rates across all studies was 36% (95% CI: 17%–57%; I<sup>2</sup>: 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.<sup>9</sup> 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.<sup>10</sup> 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.

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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.<sup>6,11,12</sup> Two of these reviews called for additional RCTs that evaluated standardized clinical outcomes to establish the safety and efficacy of bulking agents.<sup>6,11</sup>

Percutaneous Tibial Nerve Stimulation

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.<sup>13</sup> 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.

In 2021, Hayes published an updated comparative effectiveness review evaluating PTNS for the treatment of non-neurogenic overactive bladder syndrome.<sup>14</sup> 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.

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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, given 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.

Sacral Nerve Stimulation

*Systematic Reviews*

In 2010 (updated 2014; archived 2015), Hayes evaluated the safety and efficacy of sacral nerve stimulation (SNS) for the treatment of urinary voiding dysfunction.<sup>15</sup> 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

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(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  $\geq$  5-year follow-up. Evidence was insufficient to demonstrate the efficacy of SNS 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.

*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.<sup>16</sup> 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.<sup>17</sup> 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.<sup>18</sup> 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.<sup>19</sup>

Pelvic Floor Electrical Stimulation

In 2020, 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).<sup>2</sup> 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,

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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.

*Women with Urge Urinary Incontinence*

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**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.

*Men with Stress Urinary Incontinence*

**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.<sup>20</sup> 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

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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 to 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.<sup>3</sup> 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 2018, ECRI evaluated the efficacy of ProAct adjustable continence therapy for the treatment of male stress urinary incontinence (SUI).<sup>4</sup> Having searched the literature through May 2018, ECRI included 7 studies for review (1 systematic review, 1 retrospective comparison, 5 case series), yielding a patient size of 1,012. The systematic review reported efficacy across five studies (n=341), ranging from 62% to 68%. Reported complications included erosion (3.2% to 10.9%) and malfunction/displacement (4% to 7%). One multicenter, single-arm study reported a ≥50% reduction in pad weight in 46% of patients at 18 months. A post-hoc analysis reported that 28% of patients achieved a clinically significant reduction in the amount of daily urine leakage. One case series reported symptom improvement rates of 59% to 80% (four studies); quality of life (QOL) improvements (two studies), patient satisfaction (53%; one study), and explanation rates (18% to 30%; four studies). Limitations of reviewed studies included a lack of RCTs, small sizes of individual studies and inadequate follow-up. ECRI concluded that “very low-quality evidence suggests ProACT therapy may improve symptoms up to two years for some patients with SUI after prostate surgery.”<sup>4</sup>

*Non-randomized Studies*



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Since the ECRI review,<sup>4</sup> discussed above, two non-randomized studies published results evaluating ProACT's safety and efficacy among 294 patients.<sup>21,22</sup> 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.<sup>21</sup>

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.<sup>23</sup>

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.<sup>24</sup> 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, genitorurinary pain, hematuria, bladder spasms, asymptomatic bacteriuria, vulvar, vaginal and urethral disorders.

## **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.<sup>25</sup>

In 2017, the American Urological Association (AUA) stated that artificial urinary sphincters may be used in patients with a non-mobile urethra.<sup>26</sup>

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."<sup>25</sup>

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.<sup>26</sup> 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

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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.”<sup>27</sup>

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 toxinA or percutaneous sacral nerve stimulation.”<sup>25</sup>

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).<sup>28</sup> 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.”<sup>25</sup>

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.<sup>27</sup>

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.<sup>27</sup>

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.<sup>25</sup>

**POLICY SUMMARY**

For urinary incontinence 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

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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 to establish treatments’ safety and efficacy.

**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 Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

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.

**REGULATORY STATUS**

Food and Drug Administration (FDA)

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

- **Artificial Urinary Sphincter:** The Artificial Urinary Sphincter<sup>29</sup>
- **Bulking Agents:** Contigen,<sup>30</sup> Coaptite,<sup>31</sup> Durasphere,<sup>32</sup> Macroplastique,<sup>33</sup> URYX<sup>34</sup>
- **Percutaneous Tibial Nerve Stimulation:** Urgent PC Neuromodulation System<sup>35</sup>
- **Sacral Nerve Stimulation:** Medtronic Interstim® Sacral Nerve Stimulation™ System<sup>36</sup>
- **Pelvic Floor Electrical Stimulation:** NeoControl® Pelvic Floor Therapy System;<sup>37</sup> MyoTrac Infiniti,<sup>38</sup> ApexM,<sup>39</sup> In Tone®MV.<sup>40</sup>
- **Adjustable Continence Therapy:** ProACT™ Adjustable Continence Therapy for Men<sup>41</sup>
- **Intraurethral valve-pump:** InFlow™ Intraurethral Valve-Pump (Vesiflo, Inc.)

Mental Health Parity Statement

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.

**MEDICAL POLICY CROSS REFERENCES**

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- Pharmacy Policy: Botulinum Toxin
- Urinary Incontinence Treatments (Medicare Only)

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