

02.01.79 Miscellaneous Investigational Therapies and Tests for Urinary Incontinence/Urinary Dysfunction

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Related Policies:

- [02.01.51 Fecal Incontinence Management](#)
- [02.01.73 Biofeedback as a Treatment of Urinary Incontinence](#)
- [02.01.75 Artificial Urinary Sphincter](#)
- [02.01.76 Periureteral Bulking Agents for Treatment of Stress Urinary Incontinence](#)
- [02.01.77 Periurethral Bulking Agents for Treatment of Vesicoureteral Reflux](#)
- [02.01.78 Percutaneous and Implantable Posterior Tibial Nerve Stimulation](#)
- [08.01.21 Sacral Nerve Neuromodulation/Stimulation](#)

Summary

Description

There are numerous treatments available for individuals with urinary incontinence/dysfunction. This policy addresses miscellaneous investigational treatments, devices, and tests not addressed in a separate policy. The main criterion for inclusion in this policy is the limited evidence on the net health outcome of the treatment.

Summary of Evidence

For individuals who have urinary incontinence who receive electrical pelvic floor stimulation (PFS), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life (QOL), and treatment-related morbidity. Findings from systematic reviews have not found that electrical PFS used to treat urinary incontinence in women consistently improves the net health outcome compared with placebo or other conservative treatments. Moreover, meta-analyses of RCTs have not found a significant benefit of electrical PFS in men with postprostatectomy incontinence compared with a control intervention. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have urinary incontinence who receive magnetic PFS, the evidence includes RCTs and 2 systematic reviews. Relevant outcomes are symptoms, change in disease status, QOL, and treatment-related morbidity. A systematic review of RCTs on magnetic PFS for urinary incontinence in women concluded that the evidence was insufficient due to the following factors: a low number of trials with short-term follow-up, methodologic limitations, as well as heterogeneity in patient populations, interventions, and outcomes reported. One RCT evaluating magnetic stimulation for treating men with postprostatectomy urinary incontinence reported short-term results favoring magnetic PFS; however, the trial was small and lacked a sham comparator. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have urinary incontinence/urinary dysfunction who receive miscellaneous treatments, devices and tests, including but not limited to the following, laser therapy (Genityte procedure), inFlow intraurethral valve-pump and activator, transperineal implantation of permanent adjustable balloon continence device (ProACT), transvaginal and transurethral radiofrequency (Lyrette), vaginal weight training (cones), and tactile biomechanical sensor imaging, the evidence includes systematic reviews, RCTs and observational studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. For testing utilizing tactile biomechanical sensor imaging no studies were identified examining the clinical utility of this imaging. RCTs are needed. For the miscellaneous treatments and devices above, comparative RCTs to sham procedure or another treatment for urinary incontinence/dysfunction are needed to evaluate key health outcomes (urinary pad usage, 24 hour urinary leakage, clinical success rates, QOL questionnaires, and symptom score evaluation) to determine safety and efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have urinary incontinence/urinary dysfunction who receive transcutaneous tibial nerve stimulation (Vivally System), the evidence includes an RCT and a nonrandomized study. Relevant outcomes are symptoms, change in disease status, functional outcomes, QOL, and treatment-related morbidity. The results of the available studies did not show a clear benefit of transcutaneous tibial nerve stimulation. The RCT showed statistically significant improvements in the primary outcome measure. However, the primary outcome was a composite score of patient reported outcomes. A secondary analysis on individual symptoms showed no significant difference between the active therapy arm and the sham arm for voids or urgency leaks. The nonrandomized open-label, single-arm study showed statistically significant improvements in daily voids, incontinence episodes, and urgency episodes. However, minimal clinically important differences were not reported for these outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have urinary incontinence/urinary dysfunction who receive transcutaneous tibial nerve stimulation (ZIDA System), the evidence includes an RCT. Relevant outcomes are symptoms, change in disease status, functional outcomes, QOL, and treatment-related morbidity. The RCT compared the effects of ZIDA (n=21) to sham (n=19) in individuals with overactive bladder syndrome (OAB). After 12 weeks, the rate of the primary endpoint of clinical treatment success ($\geq 50\%$ reduction in urgency voids with or without incontinence or $\geq 30\%$ reduction in 24-h frequency voids) was significantly greater in the ZIDA group (80% versus 39%; $p=0.02$). A total of 5 adverse events were reported, including 4 in the ZIDA group (2 cases of urinary tract infection, 2 cases of foot pain) and 1 in the sham group (suspected COVID-19 infection). The certainty of the evidence is limited by the small sample size and lack of longer-term follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable.

OBJECTIVE

The objective of this evidence review is to determine whether one of several miscellaneous treatments and tests not addressed in a separate policy improve the net health outcome for individuals with urinary incontinence/dysfunction.

PRIOR APPROVAL

Not applicable.

POLICY

Note: For pelvic floor stimulation for the treatment of fecal incontinence see medical policy [02.01.51 Fecal Incontinence Management](#) which denies investigational for this indication.

The following treatments, devices, and tests are considered **investigational** for the treatment of urinary incontinence/urinary dysfunction due to the lack of clinical evidence demonstrating an impact on improved net health outcomes:

- Endovaginal cryogen-cooled, monopolar frequency remodeling (Viveve Treatment)
- inFlow™ intraurethral valve-pump and activator implantation;
- Ittamiocel (autologous muscle cell therapy progenitor cells)
- Laser therapy (Genityte procedure);
- Pelvic floor stimulation by any method electrical or magnetic:
 - ApexMTM
 - Detrusan™
 - Elitone Device™
 - EmbaGYN®

- Incare® PRS
- MyoTrac Infinity™
- Pathway™ CTS2000
- UROSTYM™;
- Subfascial tibial nerve stimulation (e.g., Revi System)
- Tactile biomechanical sensor imaging (transvaginal biomechanical imaging);
- Transcutaneous tibial nerve stimulation (Vivally® System and ZIDA® System)
- Transperineal implantation of permanent adjustable balloon continence device (e.g., ACT™, ProACT™);
- Transvaginal and transurethral radiofrequency energy therapies for bladder neck suspension, including, but not limited to, the Lyrette™ Transurethral SUI System (previously known as Renessa System);
- Vaginal weight training with specially designed weights (cones).

ALL Category III codes will be considered **investigational** unless the code is explicitly addressed as a covered service in a Wellmark BlueCross BlueShield Medical Coverage Policy.

Non-Covered

Urinary incontinence devices FDA approved for use without prescription for the treatment of urinary incontinence/urinary dysfunction are considered a **non-covered benefit**.

POLICY GUIDELINES

Category III codes are a set of temporary (T) codes for emerging technologies, services, and procedures that allow for data collection by the American Medical Association's (AMA). If a Category III code is available, providers must use that code instead of an unlisted or deleted Category I code. The services or procedures represented by Category III codes may not have FDA approval, may not be performed by many health care professionals across the country, and the service or procedure may not have proven clinical efficacy. Certain T codes may be addressed as a covered service in a Wellmark BlueCross BlueShield Medical Coverage Policy. But, unless there is explicit Policy criteria that specifically extends coverage to a particular Category III code, the code would generally be considered experimental, investigational, or unproven.

Coding

See the [Codes](#) table for details.

BACKGROUND

Treatments, Devices, and Tests Addressed in this Evidence Review

Laser Therapy (GeniTyte Procedure)

The GeniTyte procedure is a new treatment approach for the treatment of stress urinary incontinence. It involves the use laser that stimulates the skin's natural production of collagen making it more supple and

elastic. GeniType works to regain bladder control by tightening the tissue around the urethra. The number of treatments needed to restore the function of a woman's urethra supposedly depends largely on how much collagen is still present in her skin.

Pelvic Floor Stimulation

Pelvic floor stimulation (PFS) is proposed as a nonsurgical option for women and men with urinary or fecal incontinence. This approach involves either electrical stimulation or pelvic floor musculature or extracorporeal pulsed magnetic stimulation.

Pelvic floor stimulation (PFS) involves electrical stimulation of pelvic floor muscles using either a probe wired to a device for controlling the electrical stimulation or, more recently, extracorporeal electromagnetic (also called magnetic) pulses. Stimulation of the pudendal nerve to activate the pelvic floor musculature may improve urethral closure. In addition, PFS is thought to improve partially denervated urethral and pelvic floor musculature by enhancing the process of reinnervation. Methods of electrical PFS have varied in location (e.g., vaginal, rectal), stimulus frequency, stimulus intensity or amplitude, pulse duration, pulse to rest ratio, treatments per day, number of treatment days per week, length of time for each treatment session, and overall time period for device use between clinical and home settings. Variations in the amplitude and frequency of the electrical pulse are used to mimic and stimulate the different physiologic mechanisms of the voiding response, depending on the etiology of the incontinence (i.e., either detrusor instability, stress incontinence, or a mixed pattern). Magnetic PFS does not require an internal electrode; instead, patients sit fully clothed on a specialized chair with an embedded magnet.

Patients receiving electrical PFS may undergo treatment in a physician's office or physical therapy facility, or patients may undergo initial training in a physician's office followed by home treatment with a rented or purchased pelvic floor stimulator. Magnetic PFS may be administered in the physician's office.

Tactile Biomechanical Sensor Imaging

The Kegel perineometer or vaginal manometer was developed as an instrument to measure the strength of voluntary contractions of the pelvic floor muscles. Using the perineometer ascertains the air pressure inside the vagina when asking the woman to squeeze as hard as possible, which indicates whether doing Kegel exercises would be beneficial. Assessment of the pelvic floor strength can also be performed digitally by the physician during a gynecological exam digitally to identify women with fascial defects of the pelvic floor. The Kegel perineometer and digital examinations are said to identify those women at risk of genital prolapse or urinary incontinence.

inFlow™ Intraurethral Valve-Pump and Activator

The inFlow™ intraurethral valve-pump and activator is a urinary device for women with incomplete bladder emptying, due to impaired detrusor contractility (IDC). The inFlow™ is promoted as an alternative to urinary catheters. The device consists of a small catheter with an internal magnetically activated pump-valve mechanism which is placed in the female urethra for up to 29 days or less. Upon activation by a battery-powered wand held low over the pubic area, the valve opens and the pump induces urine flow. The device blocks urine flow when continence is desired, and an internal pump draws urine out of the bladder when activated by the user. Proper device sizing and initial insertion is done by a physician. Subsequent device replacements are self-inserted, or inserted by a caregiver, approximately every 29 days.

Subfascial Tibial Nerve Stimulation

Subfascial tibial nerve stimulation (e.g., Revi System) is an implantable tibial nerve modulation (iTNM) which involves a leadless, battery-less implant that is inserted via a minimally invasive open procedure at the tibial neurovascular bundle. The procedure requires no fluoroscopy as it is accomplished under direct visualization. Radiofrequency wireless stimulation of the implant is provided via a wearable control unit that is programmed by the clinician.

Transperineal Implantation of Permanent Adjustable Balloon Continence Device (ProACT™ Adjustable Continence Therapy)

The ProACT™ adjustable continence system consists of two postoperatively adjustable silicone balloons placed under fluoroscopic guidance at the prostatic apex (in post-TURP individuals), or at the vesico-urethral anastomosis (in post prostatectomy subjects) in males. Balloon titration is via tubing connected to a titanium port in the scrotum to enable post-implantation adjustments. The balloons are filled with isotonic solution following implantation; 1 ml can be titrated monthly until optimum continence is achieved.

Transvaginal and Transurethral Radiofrequency Energy

The Lyrette™ Transurethral SUI System: Previously known as Renessa Procedure, this procedure involves passing a specially designed 4-needle radiofrequency probe through the urethral opening into the urethra and then into the bladder. Once the probe is in position, a small balloon is inflated to keep it stationary during the procedure. Radiofrequency energy is then delivered for 60 seconds to the 4 needles, which are deployed from the probe into the tissue of the bladder neck and upper urethra. Tissue temperatures of 65 to 75 degrees Celsius are generated; at this temperature, focal microscopic denaturation of collagen occurs. The procedure is repeated 9 times so that collagen is denatured at 36 tissue sites.

Transcutaneous Tibial Nerve Stimulation

The Vivally® System is a transcutaneous tibial nerve stimulator for home use utilizing a phone application to treat individuals with urge urinary incontinence and urinary urgency caused by overactive bladder syndrome. Using proprietary algorithms and electromyographical sensors, the Vivally® System detects the level of energy being delivered to the tibial nerve during stimulation, enabling the system to evaluate the level of tibial nerve activation and autonomously adjust stimulation parameters to ensure optimal therapeutic output in a true real-time, closed-loop operation. The device is worn on the ankle for 30 minutes 3 times a week.

The ZIDA® System is a TNS device that includes a cotton blend sock (available in 4 sizes) with embedded electrodes and a detachable control unit which has 3 buttons (i.e., on/off buttons to increase or decrease stimulation). It is a wearable neuromodulation device intended to treat individuals with urinary incontinence and urgency associated with OAB. It is intended for home use once per week for 30 minutes in duration, along with behavioral and educational interventions.

Vaginal Weight Training

Vaginal weight training is a behavioral therapy that employs weights during Kegel or pelvic floor exercises to strengthen pelvic floor muscles. The use of vaginal weights (cones) has not been shown to improve pelvic floor muscle strength more than Kegel exercises alone.

Viveve Treatment

The Viveve treatment of stress urinary incontinence involves placement of a probe into the vagina that emits cryogen-cooled radiofrequency energy. The intention is for the cryogen cooling to protect the tissue from damage while the radiofrequency energy is delivered into the tissue to prompt production of collagen and improve the structural integrity of the vagina, including support of the urethra, with the goal of reducing stress urinary incontinence. The procedure is considered noninvasive or minimally invasive; it can be performed in a physician's office in approximately 30 minutes, and does not require anesthesia or sedation.

The Viveve device has received FDA clearance "for use in general surgical procedures for electrocoagulation and hemostasis" (FDA, 2020). It is not currently cleared specifically for treatment of urinary incontinence.

Regulatory Status

Pelvic Floor Stimulation

Several electrical stimulators have been cleared by the U.S. Food and Drug Administration (FDA). In 2006, the MyoTrac Infiniti™ (Thought Technology) and in 2015, the Apex®M (now Apex®; InControl Medical) nonimplanted electrical stimulators for treating urinary incontinence were cleared for marketing by the FDA through the 510(k) process. Predicate devices are also used to treat urinary incontinence, including the Pathway™ CTS 2000 (Prometheus Group) and the InCare® PRS (Hollister). In 2011, the itouch Sure Pelvic Floor Exerciser (TensCare) was cleared for marketing.

In 2000, the NeoControl® Pelvic Floor Therapy System (Neotonus) was cleared through the FDA 510(k) process for treating urinary incontinence in women. This device, formerly known as the Neotonus Model 1000 Magnetic Stimulator, provides noninvasive electromagnetic stimulation of pelvic floor musculature. The magnetic system is embedded in a chair seat; patients sit on the chair fully clothed and receive the treatment. The magnetic fields are controlled by a separate power unit.

In 2014, the InTone® MV (InControl Medical), a nonimplantable device that provides electrical stimulation and/or biofeedback via manometry, was cleared by the FDA. The device is intended to treat male and female urinary and fecal incontinence.

FDA product code: KPI.

Tactile Biomechanical Sensor Imaging (Vaginal Tactile Imager)

The Vaginal Tactile Imager is an example of an imager that has obtained FDA clearance through the FDA 510(k) process. Vaginal Tactile Imager (Advanced Tactile Imaging) obtained FDA clearance in April of 2015 through the FDA 510(k) process (K142355, Product Code=HIR). The device is indicated for "high resolution mapping of pressures to assess the strength of pelvic floor muscles within the vagina. It is used in a medical setting to acquire the pressures and store the corresponding data. It also provided visualization, analysis tools and information. The real time data as well as the analysis information can then be viewed with an intention of assisting in the diagnosis and evaluation. The device is intended for use by physicians, surgeons and medically trained personnel."

inFlow™ Intraurethral Valve-Pump and Activator

The inFlow™ intraurethral valve-pump and activator (Vesiflo, Inc.) obtained FDA clearance through the de novo approval process in 2014 and is indicated for, "Use in female individuals 18 years of age or older who have incomplete bladder emptying, due to impaired detrusor contractility of neurologic origin, and who are capable of operating it in accordance with instructions or who have trained caregivers."

Transperineal Implantation of Permanent Adjustable Balloon Continence Device (ProACT™ Adjustable Continence Therapy)

The ProACT™ was approved by the FDA in November 2015 via a premarket approval (PMA) application for treatment of men with stress incontinence of at least 12 months' duration following prostate surgery who did not respond to conservative therapy.

Transvaginal and Transurethral Radiofrequency Energy

In 2005, Novasys Medical received clearance to market the Renessa® transurethral radiofrequency system through the FDA 510(k) process. The device is indicated for the transurethral treatment of stress urinary incontinence due to hypermobility. In 2013, Verathon acquired Renessa® by Novasys Medical®, and rebranded it as the Lyrette™.

In 2002, the SURx Transvaginal System received marketing clearance through the U.S. Food and Drug Administration (FDA) 510(k) process. According to the FDA, the device "is indicated for shrinkage and stabilization of female pelvic tissue for treatment of Type II stress urinary incontinence due to hypermobility in women not eligible for major corrective surgery." As of 2006, the SURx is no longer marketed in the U.S.

Laser Therapy (GeniTyte Procedure), Vaginal Weight Training

FDA clearances were not identified for these procedures or devices.

Transcutaneous Tibial Nerve Stimulator

Table 1. Transcutaneous Tibial Nerve Stimulator Devices FDA 510 (k) Marketing Clearance

ZIDA® Wearable Neuromodulation System	Exodus Innovations	Mar 2021	K192731	Treatment of patients with an overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence
Vivally® System Wearable, Non-Invasive Neuromodulation System and Mobile Application	Avation Medical, Inc.	Apr 2023	K220454	Treatment of patients with bladder conditions of urinary incontinence and urinary urgency

Revi System

In August 2023 BlueWind Medical was granted approval (DEN220073) for Revi System, implantable tibial electrical urinary incontinence device, through FDA De novo (DEN) Classification. It is indicated for the treatment of patients with symptoms of urgency incontinence alone or in combination with urinary urgency. Product code QXM.

Flyte System

In September 2021 Pelvital USA, Inc. Flyte™ System received FDA clearance through 510k process (K212655). Indications for use “The Pelvital System is intended for the strengthening of the pelvic floor muscles, which has been found to help women with stress urinary incontinence.” In December 2023 Pelvital USA, Inc. Flyte Mechanotherapy System (aka Flyte System) (MTI-1.0), Device Name Flyte System received FDA clearance through 510k process (K233362). Indications for use “The Flyte System is intended for strengthening of the pelvic floor muscles to treat women with stress urinary incontinence.” This FDA approval notes this is an “Over the Counter (OTC)” device.

RATIONALE

This evidence review was created in September 2010 with searches of the PubMed database. The most recent literature update was performed through September 2025.

Therapy

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Test

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Miscellaneous Therapies for Urinary Incontinence/Dysfunction Not Addressed in a Separate Policy

Clinical Context and Therapy Purpose

The purpose of laser therapy (GeniType Procedure), pelvic floor stimulation, inFlow intraurethral valve-pump and activator, transperineal implantation of permanent adjustable balloon continence device (ProACT Adjustable Continence Therapy), transvaginal and transurethral radiofrequency energy, and vaginal weight training in individuals who have urinary incontinence/dysfunction is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with urinary incontinence/dysfunction. Types of urinary incontinence include stress incontinence, urgency incontinence, mixed (both stress and urgency). Types of urinary dysfunction are overactive bladder, dysfunctional voiding and underactive bladder.

Urinary incontinence is a common condition and can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that, among noninstitutionalized persons 65 years of age and older, 44% have reported issues with urinary incontinence. Urinary incontinence in women is common, with some estimates citing a 50% incidence. Factors that increase a woman's risk include older age, obesity, parity, vaginal delivery, and family history.

Urinary incontinence is less common in men, with estimates ranging from 11% to 16% in men greater than 65 years. Factors that increase a man's risk include older age, prostate disease, urinary tract infection history, impaired activities of daily living, neurologic disease, constipation, diabetes, and sleep apnea.

Urinary dysfunction (voiding dysfunction) is related to the muscles that control the flow of urine out of the body that don't relax completely, and the bladder never fully empties. This causes a range of symptoms such as daytime wetting, night wetting, a feeling that the bladder is always full, urgency and straining to urinate.

Interventions

The therapies being considered are laser therapy (GeniType Procedure), pelvic floor stimulation, inFlow intraurethral valve-pump and activator, transperineal implantation of permanent adjustable balloon continence device (ProACT Adjustable Continence Therapy), transvaginal and transurethral radiofrequency energy, and vaginal weight training (cones).

Comparators

The comparators being considered are behavioral therapies (e.g., monitoring fluid intake, bladder, and pelvic floor muscle training, diet) and external support devices (e.g., pharmacotherapy, continence pessaries, urethral bulking injection procedures).

Outcomes

The general outcomes of interest include a reduction in symptoms (e.g., number of incontinence episodes) and improvements in quality of life and cure rates. Short-term results can be measured at 6 months. Longer-term follow-up may be necessary to determine if treatment has durable effects.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Laser Therapy (GeniTyte Procedure)

No studies were identified that evaluated laser therapy (GeniTyte Procedure) as a treatment of urinary incontinence.

Section Summary: Laser Therapy (GeniTyte Procedure)

Conclusions regarding the net health benefit for laser therapy (GeniTyte Procedure) as a treatment of urinary incontinence/dysfunction could not be drawn as no published peer-reviewed studies were identified.

Electrical Pelvic Floor Stimulation

Urinary Incontinence in Genotypic XX Individuals

Systematic Reviews

A TEC Assessment (2000) concluded there was insufficient evidence that electrical PFS improved health outcomes compared with placebo or other behavioral therapies in women with stress, urge, or mixed incontinence.

Subsequently, several systematic reviews of the literature with pooled study findings have been published.

Naidu et al (2025) published a systematic review of RCTs (N=32 trials) evaluating the use of intravaginal electrical stimulation for the treatment of urinary incontinence in women. No meta-analysis was performed due to heterogeneity in protocols and trial quality. A narrative synthesis of outcomes showed that intravaginal electrical stimulation was associated with favorable within-group improvements in

incontinence symptoms, but its superiority over active comparators (eg, pelvic floor muscle training [PFMT], biofeedback) was inconsistent. Of 8 trials reporting pad use, 6 found significant reductions within intravaginal electrical stimulation groups. A pooled summary of 15 trials on pad weight found 10 reporting significant reductions post-intravaginal electrical stimulation, though differences between intravaginal electrical stimulation and active comparators were generally non-significant. Nineteen trials assessed pelvic floor muscle strength; 11 demonstrated significant within-group improvements, though PFMT often showed greater effects than intravaginal electrical stimulation. Across 27 trials assessing QOL, 15 found significant improvements in the intravaginal electrical stimulation groups, although between-group comparisons varied. Adherence to intravaginal electrical stimulation was moderate to high (61 to 100%), and adverse events were infrequent and mild (eg, irritation, discomfort).

Leonardo et al (2022) published a systematic review and meta-analysis of 8 RCTs (N=562) which evaluated the comparative effectiveness of biofeedback-assisted PFMT versus PFS versus a control group (PFMT alone, bladder training, or lifestyle recommendations only) in women with overactive bladder. Outcomes assessed included quality of life, number of episodes of incontinence, and number of patients who improved or were cured. The PFS group exhibited significant differences in quality of life (mean difference, 7.41; 95% confidence interval [CI], 7.90 to 12.92; $p=.008$), episodes of incontinence (mean difference, -1.33; 95% CI, -2.50 to -0.17; $p=.02$), and the number of patients who improved or were cured (risk ratio, 1.46; 95% CI, 1.14 to 1.87; $p=.003$) compared to the control group. The biofeedback-assisted PFMT group did not have significant differences in any of these outcomes compared to the control group. Limitations of the study include high heterogeneity for some analyses and differences in the qualitative and quantitative assessments utilized in the included RCTs which limits the direct comparability among the studies.

A 2017 Cochrane review evaluated the effect of PFS on self-reported incontinence. The review found no difference between PFS and PFMT in the likelihood of cure of stress incontinence at 6 months based on the results of 4 RCTs (N = 143; relative risk [RR], 0.51; 95% CI, 0.15 to 1.63). There was also no difference between groups in adverse event rates based on an imprecise estimate (RR, 5.00; 95% CI, 0.25 to 99). Quality of life was not reported. The same review included studies comparing PFS + PFMT versus PFMT alone, finding no difference between groups in incontinence rates based on 3 trials (n = 99; RR, 0.76; 95% CI, 0.38 to 1.52). The review found a small benefit of PFS + PFMT on incontinence-related quality of life when compared with PFMT alone (standard mean difference, -0.77; 95% CI, -1.11 to -0.42). The review deemed the evidence for PFS alone or in combination with PFMT versus PFMT alone inconclusive for incontinence and quality of life outcomes.

An Agency for Healthcare Research and Quality comparative effectiveness review prepared by Shamliyan et al (2012) identified 9 RCTs evaluating electrical intravaginal stimulation in women with urgency, stress, or mixed incontinence. Eight of the 9 studies were published in 2000 or earlier; nearly all used a sham treatment as the control. A pooled analysis of continence rates in 8 RCTs comparing electrical PFS with no active treatment yielded an RR of 2.86 (95% CI, 1.57 to 5.23). A pooled analysis of the reduction in incontinence symptoms yielded an RR of 2.01 (95% CI, 1.28 to 3.15). Reviewers concluded that a high level of evidence suggested electrical PFS is associated with increased continence rates, and that such stimulation improved urinary incontinence.

Moroni et al (2016) published a systematic review of conservative treatment for stress urinary incontinence. Five trials (N=221 women) were identified comparing intravaginal electrical PFS with control. There were insufficient data on cure rates (e.g., continence rates). A pooled analysis of 4 studies reporting urine quantity with a pad weight test found a significantly greater reduction in pad weight in the treatment versus control groups (mean difference, -9.15; 95% CI, -17.22 to -1.08). A pooled analysis of 2 studies found significantly greater improvement in the incontinence-specific quality of life in the electrical PFS group than in the control group (mean difference, -1.44; 95% CI, -1.94 to -0.95). Three studies were

included in a pooled analysis of a number of incontinence episodes; the findings were not reported. Reviewers stated that, among all conservative treatments assessed, evidence was strongest in support of PFS, with or without biofeedback, for treatment of stress urinary incontinence.

Genotypic XY Individuals With Postprostatectomy Urinary Incontinence

Systematic Reviews

Tang et al (2025) conducted a systematic review and meta-analysis comparing the effectiveness of electrical stimulation combined with pelvic floor muscle exercises (PFME) versus PFME alone for treating male urinary incontinence after radical prostatectomy. The review included 10 RCTs published between 1999 and 2024, with treatment durations ranging from 2 to 12 months. Electrical stimulation methods and devices varied across studies, including perineal, transanal, and combined approaches. Outcomes assessed included 24-hour pad test, International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), incontinence control rate, and QOL. In the short term (≤ 3 months), electrical stimulation significantly improved incontinence symptoms, with a marked reduction in ICIQ-SF scores (mean difference, -3.50; 95% CI, -5.11 to -1.89; $p < .0001$) and a doubling of continence control rates (risk ratio, 2.01; 95% CI, 1.17 to 3.44; $p = .01$), although no benefit was observed for objective leakage volume or quality of life. In contrast, long-term treatment (≥ 6 months) with electrical stimulation significantly reduced urinary leakage based on the 24-hour pad test (mean difference, -21.64; 95% CI, -40.03 to -3.25; $p = .02$), but showed no significant improvement in ICIQ-SF scores or continence rates. Analysis of QOL outcomes found no significant difference between the electrical stimulation group and the control group.

Sciarra et al (2021) conducted meta-analyses comparing the effect of PFS with PFMT and biofeedback on urinary incontinence in men following radical prostatectomy. The review included 5 RCTs of PFS, the most recent of which was published in 2018. PFS devices, frequency, and duration varied among the trials. At 3 months, the effect size for continence recovery (based on pad-free event rate) was 0.57 (95% CI, 0.46 to 0.69) for PFS, 0.40 (95% CI, 0.30 to 0.49) for PFMT, and 0.54 (95% CI, 0.32 to 0.75) for biofeedback ($p = .01$ for both PFS and biofeedback vs. PFMT). At 6 and 12 months, PFS effect sizes were 0.78 (95% CI, 0.59 to 0.98) and 0.82 (95% CI, 0.65 to 0.99), respectively, and there was no longer a statistically significant difference between any treatment group and rate of continence recovery.

A Cochrane review by Berghmans et al (2013) identified 6 RCTs on electrical PFS with nonimplanted electrodes for postprostatectomy urinary incontinence in men. The trials varied by intervention used, study protocols, study populations, and outcome measures. In a pooled analysis of 4 RCTs comparing the combination of electrical stimulation and pelvic floor muscle exercises with pelvic floor muscle exercises alone, there was no statistically significant difference between groups in the proportion of men with urinary incontinence at 3 months (RR, 0.93; 95% CI, 0.82 to 1.06). Findings from studies evaluating electrical PFS alone were not pooled. A 2023 Cochrane review on consecutive interventions for managing urinary incontinence after prostate surgery found no studies on electrical or magnetic stimulation compared with no treatment, sham, or verbal/written instructions that reported on key outcomes.

Zhu et al (2012) conducted a meta-analysis and reported similar findings for electrical PFS to treat postprostatectomy urinary incontinence. Reviewers identified 4 RCTs (N=210 men) that provided sufficient data on clinical outcomes. A pooled analysis of data from 3 trials did not find a statistically significant benefit of electrical PFS on continence levels compared with controls within 3 months of prostatectomy (RR, 1.21; 95% CI, 0.96 to 1.54). Similarly, a pooled analysis of data from all 4 trials did not show a statistically significant benefit of electrical PFS on continence levels 6 to 12 months after prostatectomy (RR, 1.03; 95% CI, 0.88 to 1.20).

Randomized Controlled Trials

No additional RCTs were identified relevant to this review.

Section Summary: Electrical Pelvic Floor Stimulation for Urinary Incontinence

A majority of RCTs on electrical PFS for treatment of women with urinary incontinence have been published before 2001. Meta-analyses of RCTs have had inconsistent findings on the impact of electrical intravaginal stimulation on urinary incontinence in women compared with sham treatment.

For the treatment of urinary incontinence in men, pooled analyses from 4 systematic reviews found inconsistent evidence on the effect of PFS on continence at 3 months (2 found significant benefit and 2 did not), and found no clear benefit of PFS at 6- and 12-month follow-up.

Magnetic Pelvic Floor Stimulation

Genotypic XX Individuals with Urinary Incontinence

Systematic Reviews

A systematic review of RCTs on magnetic stimulation for the treatment of urinary incontinence was published by Lim et al (2015). Reviewers identified 8 blinded, sham-controlled trials (N=484 patients). Treatment protocols (e.g., frequency, duration of magnetic PFS) varied among trials. The primary outcome was cure rate; only 1 trial reported this outcome, so data were not pooled. A meta-analysis of 3 studies reporting improvements in the continence rates found significantly greater improvement in the treatment group than in the sham group (RR, 2.29; 95% CI, 1.60 to 3.29). Due to the variability across trials in types of incontinence treated and/or outcome reporting, data were not pooled for other outcomes. Reviewers noted that the evidence was limited by low-quality trials with short-term follow-up.

Randomized Controlled Trials

Lim et al (2017) randomized 120 women with stress urinary incontinence to treatment with magnetic PFS (QRS®-1010 PelviCenter) or sham treatment. Patients received 2 sessions per week for 8 weeks (16 sessions). Patients who were unsatisfied after 2 months were allowed 16 additional active sessions in an open-label phase. All participating study centers were located in Malaysia. The primary endpoint of response was defined as a 5-point reduction on the International Consultation on Incontinence Questionnaire for Urinary Incontinence-Short Form (ICIQ-UI SF). A total of 45 (75.0%) patients responded at 2 months in the active treatment group compared with 13 (21.7%) patients in the sham group (RR, 3.46; 95% CI, 2.09 to 5.72; $p < .001$). At long-term follow-up (14 months), the patients who received 16 or more active sessions had improved response rates than those who received none (response rates of 68.3% to 75.0% vs. 21.1%). The study is limited by the small sample size and the limited demographic heterogeneity.

Genotypic XY Individuals With Postprostatectomy Urinary Incontinence

Systematic Review

A 2023 Cochrane review on conservative interventions for managing urinary incontinence after prostate surgery found no studies on electrical or magnetic stimulation compared with no treatment, sham, or verbal/written instructions that reported on key outcomes.

Randomized Controlled Trial

Unal et al (2025) evaluated the efficacy of magnetic stimulation in men with urinary incontinence following radical prostatectomy. Forty patients were assigned to receive either active magnetic stimulation (n=20) or sham treatment (n=20) using the Novamag NT60 therapy chair, administered twice weekly for 8 weeks (16 sessions). Primary outcomes included improvement in incontinence severity, quality of life, sexual function, depression, and anxiety. At 8 weeks, the active treatment group showed significant improvements in all measured outcomes except some subdomains of sexual function (erectile function, sexual desire, intercourse satisfaction, and overall satisfaction) and depression. In contrast, the sham group showed limited improvement, primarily in incontinence severity and bladder diary metrics. Between-group comparisons revealed greater improvements in the magnetic stimulation group in terms of incontinence severity, nocturia, incontinence episodes, QOL, orgasmic function, and anxiety ($p<0.05$). Improvement rates (75.0% vs. 26.3%), continence rates (45.0% vs. 15.8%), and treatment satisfaction (effect size $d=1.23$) were also significantly higher with magnetic stimulation.

Section Summary: Magnetic Pelvic Floor Stimulation

A systematic review of RCTs evaluating the use of magnetic PFS for urinary incontinence in women concluded that the evidence was insufficient due to the small number of trials with short-term follow-up, methodologic limitations, and heterogeneity in terms of patient populations, interventions, and outcome reporting.

A 2023 systematic review was unable to identify studies on magnetic PFS evaluating outcomes of interest in men with urinary incontinence. One RCT found that magnetic stimulation significantly improved urinary incontinence severity, quality of life, anxiety, and several sexual function parameters in men post-prostatectomy compared to sham treatment, with notably higher improvement and continence rates and treatment satisfaction.

inFlow™ Intraurethral Valve-Pump and Activator for Urinary Dysfunction

Systematic Review

Hayes (February 2025) Evolving Evidence Review regarding inFlow intraurethral valve-pump and Activator (Vesiflo Inc.) for bladder drainage in female patients with chronic urinary retention. While the current evidence may show this device may aid in bladder emptying and improve QOL in certain individuals who are able to tolerate the device, this device is associated with high rates of treatment termination mainly due to discomfort and urine leakage. Currently there is a lack of comparative studies and it remains unclear whether this device is safer or more effective than clean intermittent catheterization or indwelling or suprapubic catheterization. Also, the majority of the studies included heterogeneous patient populations. Adverse events reported included bacteriuria and urinary tract infections.

Single-Arm Observational Study

A single prospective, single-arm crossover study by Chen et al (2005) evaluated the use of the inFlow intraurethral valve-pump in 273 subjects with hypocontractile or acontractile bladder conditions. The first

88 subjects were enrolled directly into the study phase involving an 8-week baseline phase using clean intermittent catheterization (CIC), followed by a 16-week inFlow treatment phase, and a final 4-week treatment withdrawal phase. Subsequent subjects were first enrolled in a 1-week tolerability trial (n=185). Those subjects that satisfactorily passed that phase (n=139) continued to the study phase. A total of 196 of the original 273 (72%) subjects withdrew from the study. These withdrawals were attributed to initial discomfort and leakage of the device. A total of 77 subjects completed the inFlow treatment phase. Post-void residual volume was comparable during baseline CIC phase and inFlow treatment phase (20.3 ml versus 16.1 ml), with significantly improved quality of life ($p<0.001$).

Section Summary: inFlow™ Intraurethral Valve-Pump and Activator for Urinary Dysfunction

No comparative studies of inFlow™ intraurethral valve-pump and activator were identified. A single prospective, single-arm crossover evaluated the use of this device in individuals with hypocontractile or acontractile bladder conditions. Post-void residual volume was comparable during baseline and the inFlow™ treatment phase, with significantly improved quality of life. However, comparative studies that evaluated key health outcomes are still needed.

Transperineal Implantation of Permanent Adjustable Balloon Continence Device (ProaACT™ Adjustable Continence Therapy)

Systematic Reviews

A systematic review of studies on ProAct in men with SUI was published in 2019 by Larson and colleagues. No RCTs were identified. The authors included 19 studies with a total of 1264 individuals. In a pooled analysis of data on ProAct treatment, 60.2% of individuals were 'dry' at follow-up and 81.9% were either 'dry' or 'improved'. No data from any comparison intervention were reported. A pooled analysis of adverse event data from 18 studies found a 5.3% rate of intraoperative bladder or urethra perforation and a 22.2% revision rate over a mean follow-up of 3.6 years.

Tricard et al (2023) published an updated systematic review and meta-analysis of 18 noncomparative studies of adjustable continence therapy (proACT) for the treatment of male stress urinary incontinence post-prostatectomy. A total of 1570 individuals were included, with a mean follow-up of 34.7 months. The methodological quality of the included studies was described as heterogeneous. The overall dryness rate was 55.1%. The overall complication rate was 31.2% and 22.7% of individuals underwent reoperations.

Guerin et al (2023) published a systematic review of 13 retrospective or prospective case series that evaluated the ACT® balloons in females with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD). The evidence synthesis was purely narrative, with no pooled analyses undertaken. Methodological quality of the studies was described as low. Key results were as follows: "The success rates ranged from 13.6% to 68% and the improvement rates from 16% to 83%. The intraoperative complication rate ranged from 3.5 to 25% and consisted of urethral, bladder, or vaginal perforations. The rate of postoperative complications varied from 11 to 56% without major complications. Between 6% and 38% of ACT® balloons were explanted and subsequently reimplanted in 15.2–63% of cases."

Single-Arm Observational Studies

Additional single-arm studies published subsequent to the above-described systematic reviews include a retrospective series of 281 women implanted with ACT® balloons as a treatment for female stress urinary incontinence (de Guerry 2023) and a single-center series of 177 male and female with neurogenic or non-

neurogenic stress urinary incontinence (Ruggiero 2023). In the study of female stress urinary incontinence, after 1 year, 37% of participants were categorized as successes and 22.8% underwent explantation. In the study of male and female with neurogenic or non-neurogenic stress urinary incontinence, after 5 years, 61.9% achieved complete continence and 68.4% achieved device survival without failure.

Of note, the original FDA clearance (2015) was based on a prospective, multi-center, single-arm, open-label clinical study of 123 subjects in the intent-to-treat cohort.https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130018B.pdf. Subjects were followed for a minimum of 18 months following implantation with continued follow-up planned. The primary effectiveness endpoint was the average of two 24-hour pad weight measurements conducted at baseline compared to the average of two 24-hour pad weight measurements conducted at 18 months. Individual success was defined as $\geq 50\%$ reduction in 24-hour pad weight at 18 months, compared to baseline. Overall study success criteria was defined as an exact 95% binomial confidence interval lower boundary of $\geq 50\%$ success at 18 months. The success rate, which was based on the primary endpoint, was 46% (57/124) (95% CI, 37% to 55%), which did not meet the performance goal because the lower bound of the 95% CI was 37%, which is below the target responder rate of 50%. It was concluded that the study's primary effectiveness endpoint was not met.

High complication rates and/or need for revision surgery have been reported by several additional single-arm studies evaluating ProAct in men with SUI following prostate surgery (Nestler, 2018; Noordhoff 2017, Ronzi, 2019). For example, in the Nestler (2018) study, 59 of 112 implants of the ProAct system (53%) had to be revised after a median of 26 months due to rupture or dislocation/migration. Ronzi and colleagues (2019) identified complications in 70 of 102 cases (69%) including 34 migrations, 18 device failures, 28 urethral erosions and 28 cutaneous erosions.

Section Summary: Transperineal Implantation of Permanent Adjustable Balloon Continence Device (ProACT™ Adjustable Continence Therapy)

No comparative studies of transperineal implantation of permanent adjustable balloon continence device (ProACT™ Adjustable Continence Therapy) were identified. Systematic reviews of retrospective or prospective case series in men with SUI with follow-up from 2.9 to 3.6 years reported dryness rates ranging from 55.1% to 60.2% and revision/reoperation rates ranging from 22.2% to 22.7%. Another systematic review of 13 retrospective or prospective case series that evaluated the ACT® balloons in females with stress urinary incontinence due to intrinsic sphincter deficiency reported widely ranging success rates (13.6% to 68%) and reimplantation rates (15.2–63%). Comparative studies that evaluate key health outcomes are still needed.

Transvaginal and Transurethral Radiofrequency Energy

Dmochowski and colleagues reported on a multiinstitutional prospective case series of 120 consecutive women with urinary stress incontinence who underwent transvaginal RF bladder neck suspension. Enrolled patients had failed at least a 3-month trial of conservative therapy, including most commonly, pelvic floor muscle exercises or pelvic floor stimulation. Follow-up examinations at 1, 3, 6, and 12 months consisted of a history, physical examination, and urodynamic studies. In addition, each patient completed a voiding diary and quality-of-life questionnaire. A cure was defined as a negative Valsalva maneuver; improvement was defined as decreased daily episodes of pad use. A total of 73% of patients were considered cured or improved at 12 months. More than 68% of patients reported satisfaction with the treatment. The authors concluded that the results were encouraging and that a 73% 12-month success

rate suggested that this procedure had applicability for women with refractory incontinence who did not wish to undergo a more complicated surgical procedure. Ross and colleagues conducted a multicenter, prospective single-arm study that included 94 women with stress incontinence. At 1 year, the objective cure rate was 79%, based on a negative leak point pressure. Assessment of quality of life was also significantly improved. Larger controlled studies with longer follow-up were needed to further evaluate this procedure. As noted in a review of laparoscopic bladder neck suspension, initial promising results at 12 months declined to a 30% success rate at 45 months. These authors suggested that any new surgical technique for the treatment of stress incontinence should have more than 2 years of follow-up.

In 2007, Buchsbaum and colleagues published a retrospective follow-up of the transvaginal RF procedure in 18 patients, 11 with genuine stress urinary incontinence and 7 with mixed incontinence. (4) At an unspecified time greater than 3 months following treatment, 6 of the 18 patients reported no urine loss and were satisfied with the outcome, 2 patients were lost to follow-up, and 10 reported continuing symptoms of incontinence. The relation between diagnosis (i.e., genuine stress-induced or mixed incontinence) and outcome was not presented.

For transurethral radiofrequency energy, 2 publications from a single company-sponsored randomized controlled trial (RCT) were identified. Quality-of-life measures did not differ between the radiofrequency group (110 subjects) and the sham-control group (63 subjects) at 12 months; however, a subgroup analysis showed benefit in patients with moderate to severe stress urinary incontinence. The study was limited by the post hoc subgroup analysis, loss to follow-up of nearly 20%, and lack of investigator blinding. Longer-term follow-up, identification of the patient population that might benefit from the procedure, and independent replication were needed. In 2007, Appell and colleagues published 3-year follow-up data from the industry-sponsored study described above. Of 110 treated patients, 26 (24%) were available for evaluation; control subjects were not contacted. Of the 26, 5 had obtained other treatments and were not included in the analysis (not counted as failures). An additional 3 patients were not included since they had no episodes of incontinence at baseline. The authors reported that of the 18 (16%) included patients, 50% had reductions in incontinence episodes of greater than 50% (average of 3.5 daily incontinence episodes at baseline to 1.8 at 3 years after treatment). It should be noted that inclusion of all of the 26 subjects who had been contacted would result in a positive response rate of 38%. Interpretation of this study is limited due to the absence of the control group and inadequate numbers of treated patients in follow-up, along with excluding some patients from data analysis.

In 2009, Elser and colleagues published findings from an industry-sponsored prospective case series. This was a 36-month multicenter study of transurethral RF remodeling in 136 women with stress urinary incontinence caused by bladder outlet hypermobility who had failed nonsurgical treatment and were not candidates for surgical therapy. Exclusion criteria included urge incontinence or stress urinary incontinence caused by intrinsic sphincter deficiency. By 12 months, 25 patients withdrew consent, 19 were lost to follow-up, and 17 reported lack of response, resulting in 75 patients (55%) who were evaluated at the 12-month follow-up. Efficacy, based on the percentage of patients with a 50% or greater reduction from baseline in daily incontinence episodes, was reported in 68 (50%) patients. Of the 75 evaluated at 12 months, 69% (38% of 136) reported at least a 50% reduction in leaked urine (median of 15 g) from baseline, and 45% (25% of 136) were dry. One patient reported increased leaking. No serious adverse events were reported. The most common adverse events at day 3 included dysuria (5%), urinary retention (4%), post-procedure pain (3%), and urinary tract infection (3%).

Eighteen-month and 3-year follow-up data have been published. Sixty-three of 136 (46%) women who received treatment completed the 18-month follow-up, and data were available on 60 women (44% of the study population). Thirty-one of the 60 evaluable women (61.7%) reported a reduction of at least 50% from baseline in leaks due to activity. In an intention-to-treat (ITT) analysis of data from all 136 participants (last observation carried forward), 46.7% reported at least a 50% reduction in leaks from

baseline. A total of 41 women (30% of the study population) completed the 3-year follow-up evaluation. (10) According to diary data, available for 39 women, 24 (62%) reported at least a 50% reduction in leaks per day. In an ITT analysis with multiple imputations of missing data, 60% of women had at least a 50% reduction in leaks. The study is limited by a low long-term follow-up rate and lack of a control or comparison group.

Section Summary: Transvaginal and Transurethral Radiofrequency Energy

Transvaginal and transurethral radiofrequency tissue remodeling involves the use of nonablative levels of radiofrequency energy to shrink and stabilize the endopelvic fascia and are potential minimally invasive treatment options for urinary stress incontinence. There is insufficient evidence from well-conducted, randomized, controlled trials that either of these treatments improves the net health outcome compared to a sham procedure or another treatment for stress urinary incontinence.

Vaginal Weight Training

A Cochrane review published by Herbison et al (2013) identified 23 randomized controlled trials (RCTs) comparing weighted vaginal cones to a control condition in women with urinary incontinence. The authors noted that all the studies had small sample sizes, some had high drop-out rates and study quality was difficult to assess in many cases. Most studies used a similar protocol in which individuals held the cones in place twice a day for 15 minutes. Outcome measures varied widely. A comparison of interest is the efficacy of vaginal cones plus pelvic floor muscle training (PFMT) alone. Two trials addressed this comparison and neither found a significant benefit of the addition of vaginal cones. Thirteen trials compared vaginal cones and PFMT. In a pooled analysis of 4 trials, there was not a significant difference between groups in leakage episodes per day (mean difference [MD], 0.00; 95% CI, -0.20 to 0.20). Similarly, a pooled analysis of 5 trials did not find a significant difference between groups in the proportion of individuals with improvement on the pad test (risk ratio [RR], 1.10; 95% CI, 0.82 to 1.49). Four trials reported on subjective improvement of cure and this outcome significantly favored the vaginal cone group (RR, 1.01; 95% CI, 0.75 to 1.36). The ability to conduct pooled analyses was limited by variability in control interventions and outcome measures and thus a relatively small number of studies were included in the meta-analyses. In these meta-analyses, objective measures did not find a significant benefit of vaginal cones compared with PFMT.

In a small prospective study that evaluated vaginal cone therapy in a passive phase (without voluntary contractions of the pelvic floor) and an active phase (with voluntary contractions). Twenty-four women with SUI were treated and 21 women completed the 3-month study. Outcomes in the pad test favored the active phase as did pelvic floor evaluation and bladder neck mobility. Complete reversal of symptomatology was observed in 12 (57.1%) participants, and satisfaction was expressed by 19 (90.4%). This study lacked a comparison group of women who did pelvic floor exercises without the use of vaginal cones.

Section Summary: Vaginal Weight Training

A review of randomized controlled trials (RCTs) and systematic reviews studies found small sample sizes and high drop-out rates and study quality was difficult to assess in many cases. Objective measures did not find a significant benefit of vaginal cones compared other therapies such as pelvic floor muscle training (PFMT). Further RCTs are needed.

Transcutaneous Tibial Nerve Stimulation for Urinary Incontinence/Urinary Dysfunction

Clinical Context and Therapy Purpose

The purpose of transcutaneous tibial nerve stimulation in individuals with urinary incontinence/urinary dysfunction is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with bladder conditions of urinary incontinence/urinary dysfunction.

Interventions

The therapy being considered is transcutaneous tibial nerve stimulation.

- The Vivally® System, the device consists of a stimulator that is worn on the ankle and delivers electrical signals to the tibial nerve. This is typically an at-home treatment.
- The ZIDA® System, consists of a cotton blend sock (available in 4 sizes) with embedded electrodes and delivers mild electrical pulses to posterior tibial nerve. This is used as an at-home treatment.

Comparators

The following therapies are currently being used to make decisions about bladder conditions of urinary incontinence/urinary dysfunction: conservative therapies (e.g., medical management, pelvic floor muscle training, behavioral and dietary changes), medications, and SNS.

Outcomes

The general outcomes of interest are reduced symptoms (e.g., self-reported assessment of symptoms, a decrease in the number of voids per day) and improved quality of life. Outcomes are measured following the 6- to 12-week treatment regimen.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Vivally System

Randomized Controlled Trials

Goudelocke et al (2025) conducted a multicenter, prospective, randomized, double-blind, sham-controlled trial to evaluate the effectiveness and safety of a home-based, transcutaneous tibial nerve stimulation system for the treatment of overactive bladder (OAB). The study included 125 adult subjects with OAB who were randomized 1:1 to receive either active therapy with the Vivally System or sham therapy. Patients were allowed to continue concomitant OAB medications if therapy was stable and they remained on a consistent regimen throughout the study. The primary efficacy endpoint was responder rate, defined as $\geq 50\%$ reduction in daily urgency leaks or a $\geq 30\%$ reduction in daily voids from baseline, recorded on an electronic voiding diary. A secondary analysis was done for individual symptoms. Safety was evaluated through adverse event reporting. Primary results showed that in the modified Intent-to-Treat (mITT) population (N=107), the responder rate was significantly higher in the active therapy arm compared to the sham arm (83.6% vs 57.7%; $p=.032$). A secondary analysis on individual symptoms showed no significant difference between the active therapy arm and the sham arm for voids (3.7 ± 4.4 vs 3.4 ± 6.0) or urgency leaks (2.6 ± 2.6 vs 3.1 ± 4.1). There were 20 device-related adverse events; thirteen of which (65.0%) were considered mild. The most common device-related adverse event was pain or ache/cramping of the foot or ankle, which occurred in 8 patients. One out of 125 patients (0.8%) discontinued the study due to an adverse event determined to be unrelated to the system. No serious adverse events were reported. Trial characteristics and results are summarized in Tables 7 and 8. A limitation of the study is the primary efficacy endpoint was a composite of patient reported outcomes and the minimal clinically important difference was not specified. The statistical analysis was also not well described, lacking confidence intervals, p-values, and/or measures of variation for many of the outcome measure. Study relevance and study design and conduct limitations are summarized in Tables 1 and 2.

Table 2. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Goudelocke et al (2025)	US	8	NR	Individuals diagnosed with overactive bladder for at least 3 months	Transcutaneous tibial nerve stimulation (n=62)	Sham control (n=63)

NR: not reported.

Table 3. Summary of Key RCT Results

Study	Responder Rate, %	Voids, mean change from baseline	Urgency Leaks, mean change from baseline	Device-Related Adverse Events, n
Goudelocke et al (2025)	N=107	N=107	N=107	N=107
Transcutaneous tibial nerve stimulation (n=55)	83.6%	3.7 ± 4.4	2.6 ± 2.6	---

Study	Responder Rate, %	Voids, mean change from baseline	Urgency Leaks, mean change from baseline	Device-Related Adverse Events, n
Sham control (n=52)	57.7%	3.4 ± 6.0	3.1 ± 4.1	---
Total (N=107)	---	---	---	20
p-value	.032	NR	NR	---

NR: not reported.

Table 4. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Goudelocke et al (2025)				5. Clinically significant difference not specified 7. Primary efficacy endpoint was a composite score of patient reported outcomes	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 5. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Goudelocke et al (2025)					1. Power calculations not reported	3. Confidence intervals not reported for primary outcome and p-values not reported for secondary analysis 5. Incomplete description of statistical analysis; measures of variation not defined

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

^b Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of

crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Nonrandomized Studies

Goudelocke et al (2024) conducted a multicenter, open-label, single-arm study to evaluate the effectiveness and safety of a wearable transcutaneous tibial nerve stimulation system to treat OAB. The study included subjects with OAB (N=96), with a mean age of 60.8 ± 13.0 years, and 88.5% of the participants were female. The primary outcomes of interest were daily voids, incontinence, and urgency episodes, as well as quality of life (QOL) changes using The Overactive Bladder Quality of Life Questionnaire (OAB-q) and The Incontinence Quality of Life Questionnaire (I-QOL). The primary results showed significant reductions in 3-day diary parameters for daily voids (mean reduction of 2.84 ± 2.4; p<.0001), incontinence episodes (mean reduction of 1.91 ± 3.1; p<.0001), and urgency episodes (mean reduction of 3.09 ± 3.9; p<.0001) at 12 weeks. QOL improvements exceeded the minimal clinically important difference for all QOL questionnaires. There were 12 device-related adverse events, and no device-related serious adverse events. Mean therapy compliance at 12 weeks was 88.5%. Study characteristics and results are summarized in Tables 5 and 6. Some limitations include the open-label, single-arm study design, and subjects could either stay drug-naïve or remain on a stable dose of concomitant OAB medications, confounding the effect of the device itself. Also, minimal clinically important differences were not reported for the primary outcomes. After the initial 12-week intervention there were 38 discontinuations or withdrawals from the study, so long-term follow-up data at 12 months was limited.

Table 6. Summary of Key Nonrandomized Trials Study Characteristics

Study	Study Type	Country	Dates	Participants	Treatment ¹	Follow-Up
Goudelocke et al (2024)	Open-label, single-arm	US	NR	Patients with overactive bladder	Transcutaneous tibial nerve stimulation	12 weeks

NR: not reported; US: United States.

Table 7. Summary of Key Nonrandomized Trials Study Results

Study	Daily Voids at 12 Weeks, mean reduction ± 95% CI	Incontinence Episodes at 12 Weeks, mean reduction ± 95% CI	Urgency Episodes at 12 Weeks, mean reduction ± 95% CI	Device-Related Adverse Events, n
Goudelocke et al (2024)	N=96	N=96	N=96	N=96
Transcutaneous tibial nerve stimulation	2.84 ± 2.4	1.91 ± 3.1	3.09 ± 3.9	12

Study	Daily Voids at 12 Weeks, mean reduction $\pm$ 95% CI	Incontinence Episodes at 12 Weeks, mean reduction $\pm$ 95% CI	Urgency Episodes at 12 Weeks, mean reduction $\pm$ 95% CI	Device-Related Adverse Events, n
p-value	<.0001	<.0001	<.0001	---

CI: confidence interval.

ZIDA System

Randomized Controlled Trial

Cava et al (2022) compared the effects of ZIDA (n=21) to sham (n=19) in individuals with overactive bladder syndrome (OAB) from a single private medical center in Miami. Participants were 80% female and had a mean age of 68.4 years. After 12 weeks, the rate of the primary endpoint of clinical treatment success ($\geq 50\%$ reduction in urgency voids with or without incontinence or $\geq 30\%$ reduction in 24-h frequency voids) was significantly greater in the ZIDA group (80% versus 39%; $p=0.02$). A total of 5 adverse events were reported, including 4 in the ZIDA group (2 cases of urinary tract infection, 2 cases of foot pain) and 1 in the sham group (suspected COVID-19 infection). The certainty of the evidence is limited by the small sample size and lack of longer-term follow-up.

Section Summary: Tibial Nerve Stimulation for Urge Urinary Incontinence and Urinary Urgency

One RCT and one nonrandomized study evaluating the treatment of urge urinary incontinence and urinary urgency using transcutaneous tibial nerve stimulation (Vivally System) have been published to date. The results of the available studies did not show a clear benefit of transcutaneous tibial nerve stimulation. The RCT by Goudelocke et al (2025) showed statistically significant improvements in primary outcome measure. However, the primary outcome were a composite score of patient reported outcomes. A secondary analysis on individual symptoms showed no significant difference between the active therapy arm and the sham arm for voids or urgency leaks. The nonrandomized study by Goudelocke et al (2024) showed statistically significant improvements in daily voids, incontinence episodes, and urgency episodes. However, minimal clinically important differences were not reported for these outcomes.

One RCT compared the effects of ZIDA (n=21) to sham (n=19) in individuals with overactive bladder syndrome (OAB). After 12 weeks, the rate of the primary endpoint of clinical treatment success ($\geq 50\%$ reduction in urgency voids with or without incontinence or $\geq 30\%$ reduction in 24-h frequency voids) was significantly greater in the ZIDA group (80% versus 39%; $p=0.02$). A total of 5 adverse events were reported, including 4 in the ZIDA group (2 cases of urinary tract infection, 2 cases of foot pain) and 1 in the sham group (suspected COVID-19 infection). The certainty of the evidence is limited by the small sample size and lack of longer-term follow-up.

Miscellaneous Tests for Urinary Incontinence Not Addressed in a Separate Policy

Clinical Context and Test Purpose

The purpose of tactile biomechanical sensor imaging (transvaginal biomechanical imaging) is to quantify pelvic muscle defects that contribute to urinary incontinence.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with urinary incontinence. Types of urinary incontinence include stress incontinence, urgency incontinence, and mixed (both stress and urgency).

Urinary incontinence is a common condition and can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that, among noninstitutionalized persons 65 years of age and older, 44% have reported issues with urinary incontinence. Urinary incontinence in women is common, with some estimates citing a 50% incidence. Factors that increase a woman's risk include older age, obesity, parity, vaginal delivery, and family history.

Urinary incontinence is less common in men, with estimates ranging from 11% to 16% in men greater than 65 years. Factors that increase a man's risk include older age, prostate disease, urinary tract infection history, impaired activities of daily living, neurologic disease, constipation, diabetes, and sleep apnea.

Interventions

The test being considered is tactile biomechanical sensor imaging (transvaginal biomechanical imaging).

Comparators

The comparator of interest is standard care without tactile biomechanical sensor imaging.

Outcomes

The outcomes of interest are test accuracy, validity, and clinical utility, change in disease status and morbid events.

Study Selection Criteria

For the evaluation of clinical validity of tactile biomechanical sensory imaging, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
- Included a suitable reference standard (describe the reference standard)
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Clinically Useful

A test is clinically useful if the use of the results inform management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

No studies examining clinical utility were identified.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

It is not possible to construct a chain of evidence for clinical utility due to the lack of evidence on clinical validity.

Section Summary: Clinically Useful

There is a lack of evidence on the use of tactile biomechanical sensor imaging to manage individuals with urinary incontinence. Studies are needed that compare the use of tactile biomechanical sensory imaging with standard care without the testing and evaluate the impact on management decisions and the net health outcome of care.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are

informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Physicians

The American College of Physicians (2014) issued guidelines on the nonsurgical management of urinary incontinence. None of the miscellaneous therapies and tests included in this review were addressed in this guideline.

American Urological Association and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction

In 2019, the American Urological Association (AUA) and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) published updated guidelines on the diagnosis and treatment of non-neurogenic overactive bladder in adults. The guidelines included a statement that clinicians may offer PTNS as a third-line treatment option in carefully selected patients. The statement carried a grade C rating, indicating that the balance of benefits and risks/burdens are uncertain. In 2024, the AUA/SUFU published a guideline on the diagnosis and treatment of idiopathic overactive bladder. In the unabridged version of the guideline, PTNS is mentioned as a minimally invasive therapy option. The guideline states that "Clinicians may offer minimally invasive procedures to patients who are unable or unwilling to undergo behavioral, non-invasive, or pharmacologic therapies (Clinical Principle)" and "Clinicians may offer patients with OAB, in the context of shared decision making, minimally invasive therapies without requiring trials of behavioral, non-invasive, or pharmacologic management (Expert Opinion)". Transcutaneous tibial nerve stimulation is included in the list of non-invasive therapies in these guidelines. This guideline still does not specifically address electrical or magnetic PFS as treatment options.

In 2019 (amended 2024), AUA/SUFU/GURS also published guidelines on Incontinence after Prostate Treatment (Sandhu 2019).

Pelvic floor muscle training/exercise is recommended as first-line treatment for post-prostatectomy incontinence.

Other miscellaneous therapies and tests included in this review were not addressed in this guideline.

Related guideline statements include:

- Guideline Statement #22: "Adjustable balloon devices may be offered to patients with mild stress urinary incontinence after prostate treatment. (Moderate Recommendation; Evidence Level: Grade B)."
- Guideline Statement #24: "In men with stress urinary incontinence after primary, adjuvant, or salvage radiotherapy who are seeking surgical management, artificial urinary sphincter is preferred over male slings or adjustable balloons. (Moderate Recommendation; Evidence Level: Grade C)."

National Institute for Health and Care Excellence

In 2019, the NICE issued guidance on the management of urinary incontinence in female individuals. The NICE stated that electrical stimulation, alone or as an adjunct to pelvic floor muscle training, should not be routinely used to treat women with overactive bladder. The NICE guidance further stated: "electrical

stimulation and/or biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy." Magnetic PFS is not mentioned.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	0487T	Biomechanical mapping, transvaginal, with report
	0596T	Temporary female intraurethral valve-pump (i.e., voiding prosthesis); initial insertion, including urethral measurement (inFlow™ intraurethral valve-pump implantation)
	0597T	Temporary female intraurethral valve-pump (i.e., voiding prosthesis); replacement (inFlow™ intraurethral valve-pump implantation)
	0672T	Endovaginal cryogen-cooled, monopolar radiofrequency remodeling of the tissues surrounding the female bladder neck and proximal urethra for urinary incontinence
	0817T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (e.g., array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial [Revi System]
	0819T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subfascial [Revi System]
	1000T	Autologous muscle cell therapy, harvesting of muscle progenitor cells, including ultrasound guidance, when performed
	53451	Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance (ProACT™ System)
	53452	Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance (ProACT™ System)
	53453	Periurethral transperineal adjustable balloon continence device; removal, each balloon (ProACT™ System)
	53454	Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume (ProACT™ System)
	53860	Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence

	53899	Unlisted procedure, urinary system (may be indicated for extracorporeal magnetic intervention [ExMi] pelvic floor stimulation)
	58999	Unlisted procedure, female genital system (nonobstetrical) (may be indicated for extracorporeal magnetic intervention [ExMi] pelvic floor stimulation)
	97039	Unlisted modality (specify type and time if constant attendance) (may be indicated for Vaginal weight training with specially designed weights [cones])
	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		
	E0715	Intravaginal device intended to strengthen pelvic floor muscles during kegel exercises (Flyte® System)
	E0716	Supplies and accessories for intravaginal device intended to strengthen pelvic floor muscles during kegel exercises (Flyte® System)
	E0737	Transcutaneous tibial nerve stimulator, controlled by phone application
	E0740	Incontinence treatment system, pelvic floor stimulator, monitor, sensor, and/or trainer
	E1399	Durable Medical Equipment, miscellaneous
Type of Service	Various	
Place of Service	Outpatient	

POLICY HISTORY

Date	Action	Action
December 2025	Interim Review	Policy Revised
September 2025	Annual Review	Policy Revised
September 2024	Annual Review	Policy Revised
August 2023	Annual Review	Policy Revised
July 2022	Interim Review	Policy Revised

Date	Action	Action
June 2022	Annual Review	Policy Revised
April 2022	Interim Review	Policy Revised
June 2021	Annual Review	Policy Revised
June 2020	Annual Review	Policy Revised
June 2019	Annual Review	Policy Revised
June 2018	Annual Review	Policy Revised
June 2017	Annual Review	Policy Revised
July 2016	Annual Review	Policy Revised
July 2015	Annual Review	Policy Revised
August 2014	Annual Review	Policy Renewed
May 2014	Interim Review	Policy Revised
September 2013	Annual Review	Policy Revised
October 2012	Annual Review	Policy Renewed
October 2011	Annual Review	Policy Renewed
September 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
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Des Moines, IA 50306-9232

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