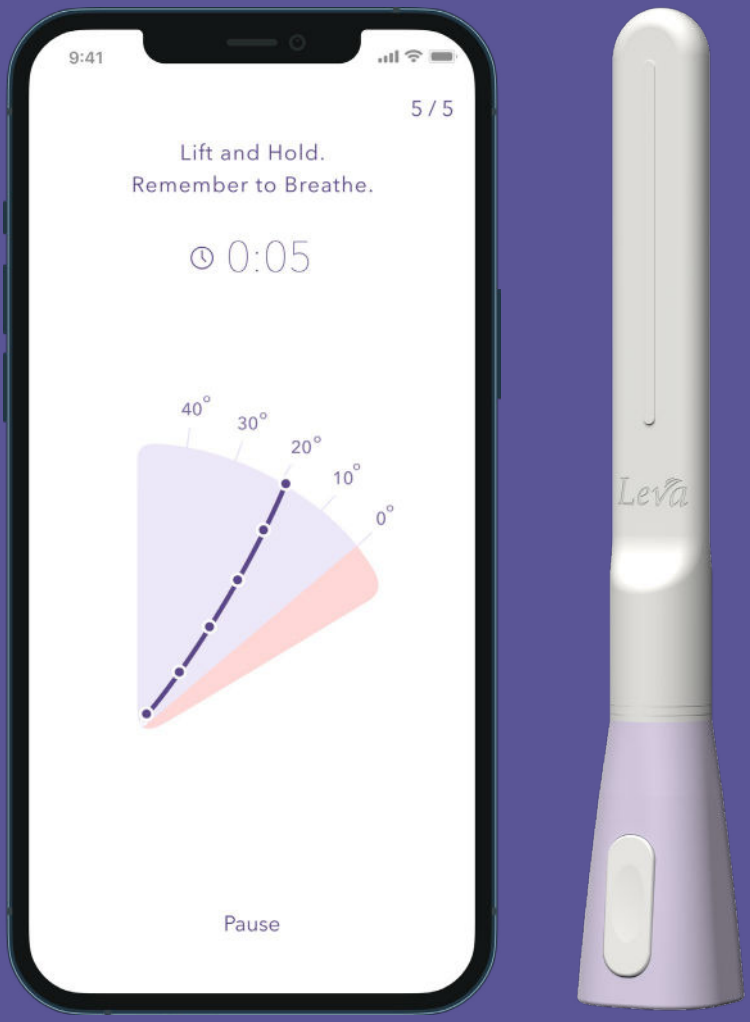
Leva® PELVIC HEALTH SYSTEM

Overview And Clinical Evidence Summary

2025



Axena HEALTH

Contents

Executive Summary and FDA Regulatory Clearance Status

What is *Leva*®?

The *Leva*® Pelvic Health System (*Leva*) is an FDA-cleared medical device indicated for the treatment of female stress, mixed, and mild-to-moderate urgency urinary incontinence, including overactive bladder (OAB). *Leva* is available by prescription only. The device is used by women outside the traditional clinic setting and is designed to support supervised pelvic floor muscle training (PFMT) – the cornerstone of first line care for urinary incontinence.

How *Leva* works

The *Leva* Pelvic Health System combines motion-based, multi-sensor technology embedded in a flexible intravaginal wand with clinical software to facilitate supervised PFMT. The intravaginal wand utilizes accelerometers (i.e., motion sensors) to recognize movement during pelvic floor muscle (PFM) contractions. Integrated software depicts this motion in real-time to enable the patient to perform PFMT correctly and consistently. The patient visualizes the motion that occurs with each PFM contraction, as well as the return to baseline during relaxation. If an incorrect motion is detected by the sensors embedded in the intravaginal wand (e.g., bearing down), the integrated software instructs the patient to correct their technique.

Additional software features include a library of educational and motivational materials curated by expert pelvic floor physical therapists. Both video and written content provide the patient with evidence-based pelvic health education and lifestyle strategies. The software also includes validated symptom surveys to enable symptom tracking. Prescribing clinicians receive provider reports to monitor PFMT adherence and symptom improvement. Additionally, the *Leva* Women's Center's care management team interacts directly with patients to further instruct and monitor the supervised PFMT program.

Is *Leva* effective?

Published data from peer-reviewed clinical studies and real-world evidence about the *Leva* device demonstrate statistically and clinically significant improvement in urinary symptoms over 8-12 weeks of use.[1–5] These outcomes are comparable to, if not exceeding, the results reported for well-known, reimbursed treatments in this category. Rigorous trials and real-world feedback confirm that the *Leva* device delivers measurable and meaningful benefits, aligning with the highest standards of evidence-based medicine. This positions *Leva* as a competitive and equally effective alternative to traditional treatment options, offering patients a proven solution for urinary symptom relief.

Food and Drug Administration (FDA) Regulatory Clearance Status

The *Leva* Pelvic Health System is an FDA-cleared, prescription-only medical device indicated for:

> Rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed and mild to moderate urgency urinary incontinence (including overactive bladder) in women.

The *Leva* Pelvic Health System is a Class II medical device and was authorized by the FDA through a 510(k) Pre-Market filing (K213913).

Female Urinary Incontinence: *The Problem*

Table 1. Common Subtypes Of Female Urinary Incontinence: Definitions

Stress urinary incontinence (SUI): involuntary urine loss that occurs with coughing or sneezing, physical activity, or exertion

Urgency urinary incontinence (UUI): involuntary urine loss that occurs with the urge to urinate

Mixed urinary incontinence (MUI): involuntary urine loss that occurs with the urge to urinate AND with physical activity, coughing or sneezing; a combination of symptoms of stress and urgency urinary incontinence

Reference: Haylen BT, De Ridder D, Freeman RM, et al. An International Urogynecological Association / International Continence Society Joint Report on the Terminology for Female Pelvic Floor Dysfunction. Neurourol Urodyn. 2010;29:4-20. doi:10.1007/s00192-009-0976-9

Urinary incontinence (UI) is defined as the "complaint of an involuntary loss of urine." The most common subtypes of female UI include stress, urgency, and mixed UI (Table 1).[6]

Over 78 million women in the United States experience UI, and over 28 million report moderate to severe symptoms.[7] Prevalence among adult community dwelling women is over 62%, and both prevalence and symptom severity increase with age.[7,8] These estimates are projected to rise, due in large part to the size of the aging demographic and the national obesity epidemic, both of which are independently associated with increased risk of UI.[7]

Incidence of UI during pregnancy is approximately 21.7%,[9] and the rate of new onset UI in the 6-month postpartum period is 21%.[10] Similarly, the incidence of UI in women at midlife is 21.9% with a remission rate of 33.3%.[11] Though remission of UI symptoms may occur in younger age groups, a significant predictor of incident UI in older women is a prior history of UI (Odds Ratio (OR) Stress OR=30.7, Urgency OR=47.4, Mixed OR=42.1).[12]

The significant economic, psychosocial, and physical burden of UI is well-documented.[13–15] Total annual cost of management and treatment of urgency UI was projected to reach $82.6 billion in 2020.[16] A health economics analysis of women with stress or mixed UI with age and comorbidity matched controls identified significantly higher health care resource utilization and costs among women with UI in the two years following their diagnosis.[17]

Table 2. Urinary Incontinence as a Significant Risk Factor

Women with UI:

- 30% greater risk of hospitalization[1]
- Twice as likely to be admitted to a nursing facility[1]
- More likely to experience falls[2*]
- More likely to report not being physically active in the last month[2*]
- Three times greater odds of functional dependence[2*]
- Twice as likely to receive care for activities of daily living (ADLs) or instrumental ADLs3 (e.g. cooking, shopping)

1. Thom DH, Haan MN, Van Den Eeden SK. Medically recognized urinary incontinence and risks of hospitalization, nursing home admission and mortality. Age Ageing. 1997;26(5):367-374. doi:10.1093/ageing/26.5.367
2. Erekson EA, Ciarleglio MM, Hanissian PD, Strohbehn K, Bynum JP, Fried TR. Functional disability and compromised mobility among older women with urinary incontinence. Female Pelvic Med Reconstr Surg. 2015;21(3):170-175. doi:10.1097/SPV.0000000000000136
3. Yang E, Lisha NE, Walter L, Obedin-Maliver J, Huang AJ, Mas /. Urinary Incontinence in a National Cohort of Older Women: Implications for Caregiving and Care Dependence. doi:10.1089/jwh.2017.6891

* Denotes women with daily UI

Compared to continent women, those with UI report greater rates of depression, anxiety, and social isolation and score lower on quality-of-life measures.[15,18] Women with UI experience greater disability and are likely to reduce physical activity as a result of UI symptoms, contributing to greater and faster functional decline over time.[19–21] Among older adults UI represents a significant risk factor for increased care needs and care dependency (Table 2).

Most women with UI in the US do not discuss their symptoms with a healthcare provider, and thus, do not initiate care. In fact, as few as 25% of women with UI in the US seek care for their condition.[22] At an individual level, barriers to care-seeking include embarrassment, lack of knowledge of treatment options, feeling that the symptoms are not bad enough, and unwillingness to bring it up independently of being asked by their HCP.[23–25] At a health systems level, structural barriers include time-constraints, competing priorities, insufficient health workforce, and socio-cultural barriers that limit patient accessibility to health services.[26–28]

Female Urinary Incontinence: *Current Treatment Options*

Introduction to Female Urinary Incontinence (UI) and Care Pathway

There is broad international and multidisciplinary agreement on most components of the UI care pathway, including adopting a stepwise approach (Figure 1).[29,30] Universal consensus for first line care for stress, urgency, and mixed UI includes pelvic floor muscle training (PFMT) and other behavioral modifications, such as bladder training, dietary changes and/or fluid titration.[30–34] PFMT is defined as "exercises for improving PFM strength, endurance, power and/or relaxation."[35] Level I evidence supports PFMT effectiveness and describes this intervention as most effective when performed under supervision (often by a physical therapist or advanced practice provider) for a period of at least 12-weeks.[36] Components of first line care are considered minimal or no risk and may also play a role in multimodal therapy, implemented alongside advanced interventions.

Medications and Non-Surgical Interventions

Beyond first line care, remaining treatment interventions for UI address either stress UI or urgency UI (or the respective component of mixed UI) (Figure 1). While pessaries may be helpful for women with stress UI, there are no FDA-approved medications for stress UI available in the US.[30,31,37] Of the medications approved for urgency UI, anticholinergics are most frequently prescribed; however, these must be used cautiously, in light of mounting evidence of increased dementia risk associated with chronic use.[38] Beta-agonists are approved for urinary urgency and urgency UI, and are becoming more commonly prescribed due to fewer side effects and thus, greater tolerance and adherence among patients.[30,32,33,37] Limitations in utilization of beta-agonists may be financial in nature, as they are more costly to patients and payers compared to anticholinergics.[39,40]

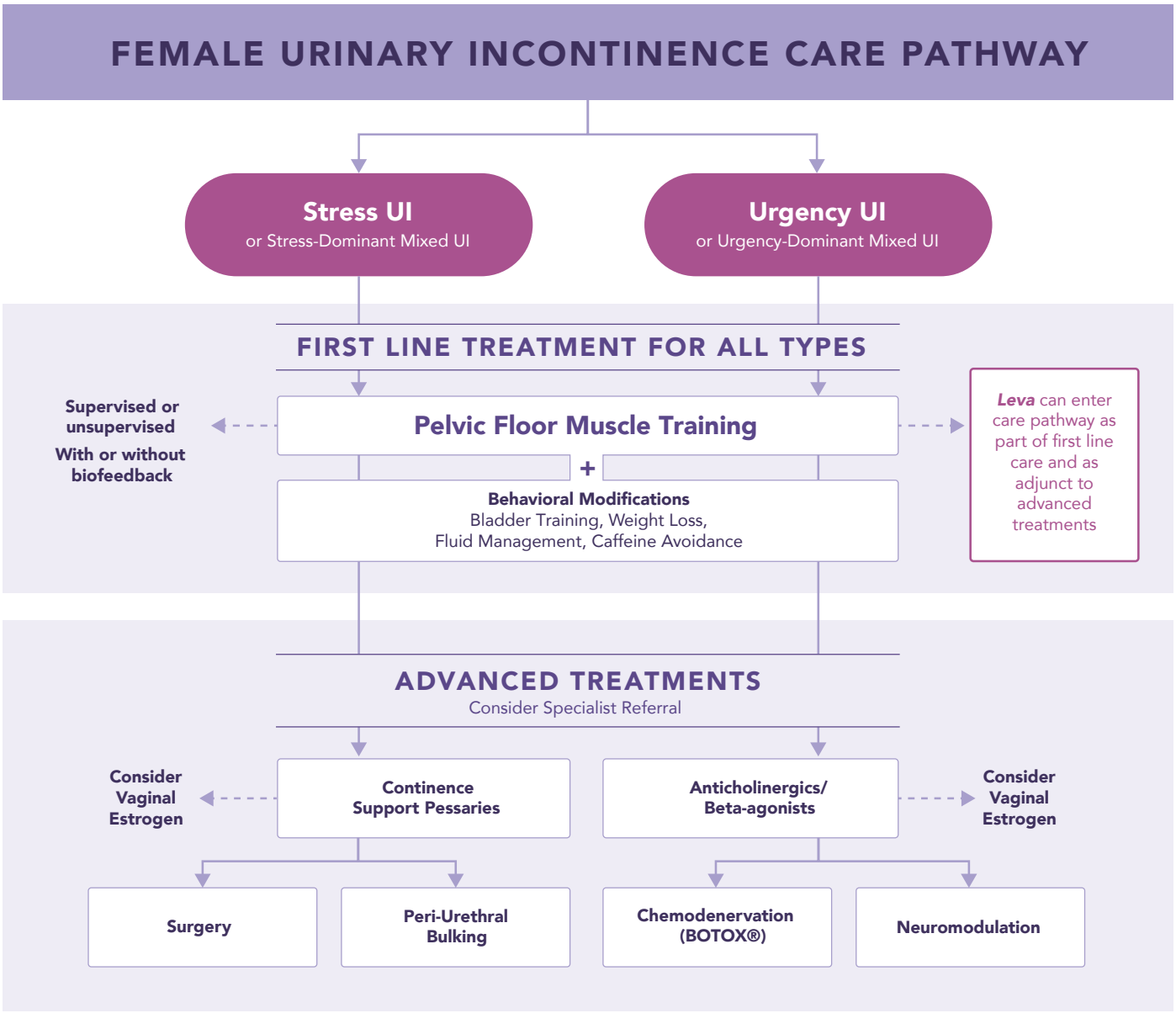
Advanced Therapies and Surgical Interventions

Advanced therapies for UI are often carried out at the specialist or subspecialist level. For stress UI, advanced therapies may include periurethral bulking agents and numerous surgical options.[30,31,37] According to a recent research report, synthetic mid-urethral sling or urethropexy are among the most commonly performed surgical interventions for stress UI, and the surgical management phase of stress UI management includes the most intensive use of resources and highest costs (when compared to nonsurgical, preoperative, and postoperative care). Patient comorbidities and surgical morbidity may influence cost and outcomes, as well.[41] For urgency UI, advanced therapies include intravesical Botox® and in-office or implantable peripheral and sacral neuromodulation.[30,33,37] Sacral neuromodulation is a guideline-recommended third-line treatment when patients with urgency UI have not had success with conservative treatments. It involves the implantation of a tined lead and neurostimulator across one or two procedures for rechargeable and non-rechargeable device, respectively.[42,43]

Despite UI care pathway recommendations by professional societies, including the American College of Obstetricians and Gynecologists (ACOG), American Urogynecologic Society (AUGS), American Urological Association (AUA), American Academy of Family Physicians (AAFP) and the United Kingdom's National Institute for Health and Care Excellence (NICE), screening and adherence to clinical guidelines is inadequate. Most women receive no treatment.[22] Of those who receive care, pharmacologic and surgical interventions are commonly offered before documented first line PFMT and behavioral interventions.[44]

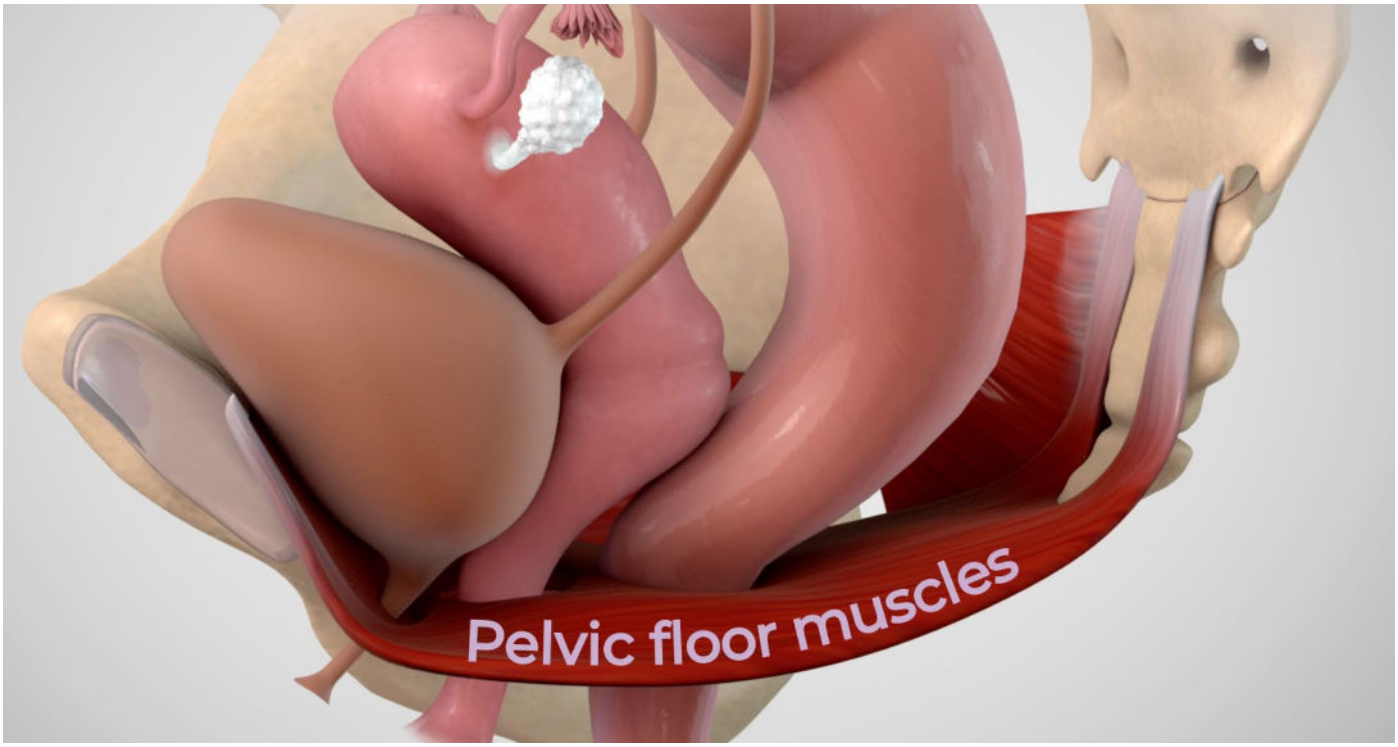
Evidence suggests that PFMT may be as effective as surgery for up to 50% of women with stress UI.[45]

Figure 1. Female Urinary Incontinence Care Pathway



1. Urinary Incontinence in Women. Practice Bulletin No. 155. American College of Obstetricians and Gynecologists. Obstet Gynecol 2015; 126:e66-81.
2. Kobashi KC, Albo ME, Roger R et al. Surgical treatment of female stress urinary incontinence: AUA/SUFU guideline. J Urol. 2017 Oct;198(4):875-883.
3. Qaseem A, Dallas P, Forciea MA, Starkey M, Denberg TD. Clinical Guideline Nonsurgical Management of Urinary Incontinence in Women: A Clinical Practice Guideline From the American College of Physicians. 2014; (September 2013). doi:10.7326/M13-2410
4. Hu JS, Pierre EF. Urinary Incontinence in Women: Evaluation and Management. Am Fam Physician. 2019;100(6):339-348.
5. Society of Urodynamics, Female Pelvic Medicine, Urogenital Reconstruction Foundation (SUFU) Overactive Bladder Clinical Care Pathway; https://sufuorg.com/docs/oab/sufu-oab-flyer.aspx; Accessed 25Sep2020.

Rationale for Pelvic Floor Muscle Training



How does pelvic floor muscle training treat urinary incontinence?

The continence mechanism relies on the physiologic action of the PFM. A correct PFM contraction involves a squeezing motion, whereby the urethral and vaginal openings are compressed, coupled with a lifting motion that causes a cranioventral (up and forward) shift of the pelvic organs. This motion lifts and stabilizes the bladder neck, provides urethral support, and closes the urethral opening.[46,47]

An adequate PFM contraction can counteract increases in intraabdominal pressure (e.g., from coughing or lifting), in order to maintain continence.[36] When these muscles become damaged, weakened, or dysfunctional, they are unable to counteract increases in intraabdominal pressure, leading to stress UI. Improving PFM tone and function also reduces urgency UI symptoms. This is possible because a PFM contraction can effectively inhibit a detrusor (bladder smooth muscle) contraction and suppress the sudden urge to void, thus allowing the individual to reach the toilet in time to avoid urine leakage.[36]

Though Level I evidence supports the application of PFMT to improve and/or resolve UI symptoms,[36] uptake and adherence to PFMT programs remains suboptimal with multiple individual and institutional barriers to care.[23,26,27] These include limited patient knowledge about how to perform PFMT and limited access to care due to a deficit of skilled providers (e.g., physical therapists, continence nurse specialists).[27,48] In the absence of supervised care, women may embark on an unsupervised PFMT regimen, often with limited efficacy.[49] Successful PFMT relies on correct exercise performance at sufficient intensity, frequency, and duration. At-home treatments such as the *Leva* Pelvic Health System with its proven clinical outcomes may facilitate adherence to PFMT for this population.

The *Leva* Pelvic Health System: *Overview*

The *Leva* Pelvic Health System is an FDA-cleared, prescription medical device used at home for the treatment of stress, mixed and mild-to-moderate urgency UI, including overactive bladder in women. *Leva* combines hardware and software to direct supervised PFMT.

The system incorporates several key components:

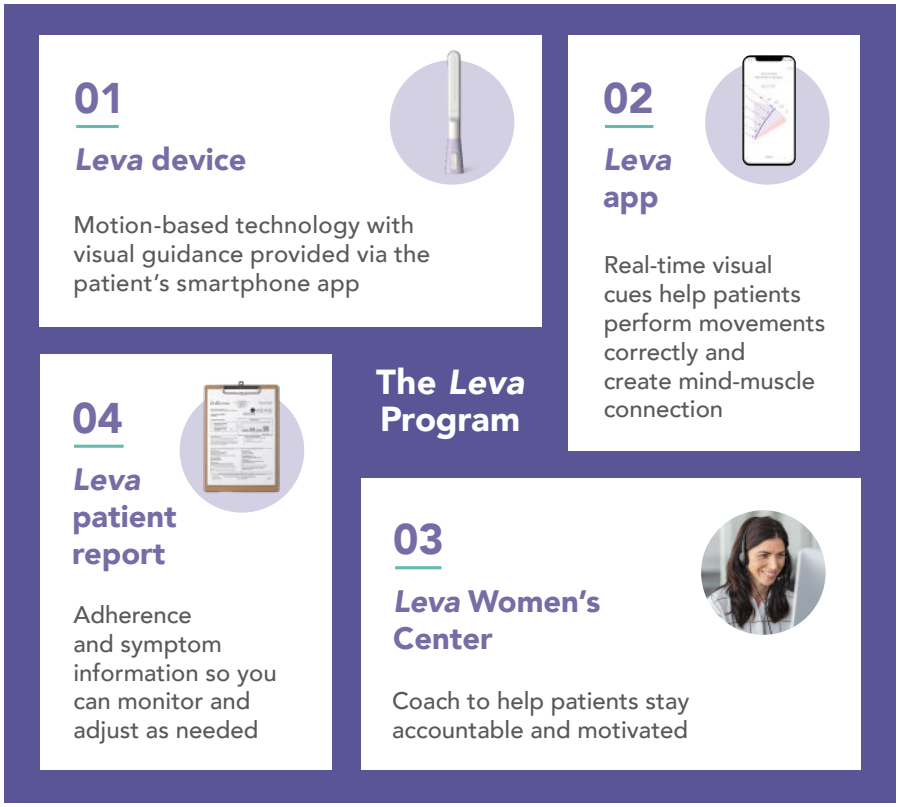
- *Leva*'s small, flexible intravaginal wand incorporates accelerometers (i.e., motion sensors), that detect the movement produced during PFM contraction (and relaxation). The *Leva* software visually depicts this motion in real-time to enable patients to perform supervised PFMT correctly and consistently.

  Leva is designed for use in standing, as the sensors function in relationship to gravity. Patients can see the 'lift-and-squeeze' motion that occurs with each muscle contraction, as well as the return to baseline during relaxation. The *Leva* software also provides feedback if the patient performs an incorrect motion, such as bearing down; thus, enabling the user to correct their technique and optimizing PFM performance.

- In addition to guiding the patient through supervised PFMT, the *Leva* software (a) passively monitors adherence to PFMT, (b) captures symptom information at 4-week intervals, using validated, patient reported outcome measures (e.g., Urogenital Distress Inventory – UDI-6),[50,51]
  (c) delivers relevant educational content in the form of videos and written information, and (d) contains reminders and reinforcements.

Additional Features:

- The *Leva* Women's Center's care management team is available to assist patients in onboarding and troubleshooting any technical challenges, and to provide motivation for adherence to the 12-week, supervised PFMT program.
- Regular reports are delivered to prescribing clinicians to facilitate tracking of adherence and symptom improvement during the 12-week, supervised PFMT program. These reports facilitate clinician engagement, enabling the prescriber to effectively counsel their patients throughout their course of therapy.



The *Leva* Pelvic Health System: *Mechanism of Action*

The *Leva* Pelvic Health System consists of an intravaginal wand, storage case, associated batteries, and the *Leva* software (Figures 2 and 3). The intravaginal component consists of six accelerometers in series on a flexible wand that is encased in thermoplastic elastomer and is reusable by a single patient. *Leva* uses Bluetooth technology to facilitate wireless data transmission between the sensors in the intravaginal wand and the *Leva* software.

The accelerometers contained within the intravaginal wand assess the movement produced during a PFM contraction. The angle of the intravaginal axis with respect to the horizon increases when a correct PFM contraction is performed and decreases with an incorrect motion, such as bearing down (Figure 2). Patients receive real-time visual feedback via the *Leva* software that reflects this change in angle. Data is encrypted and stored on a secure server to monitor adherence and symptoms.

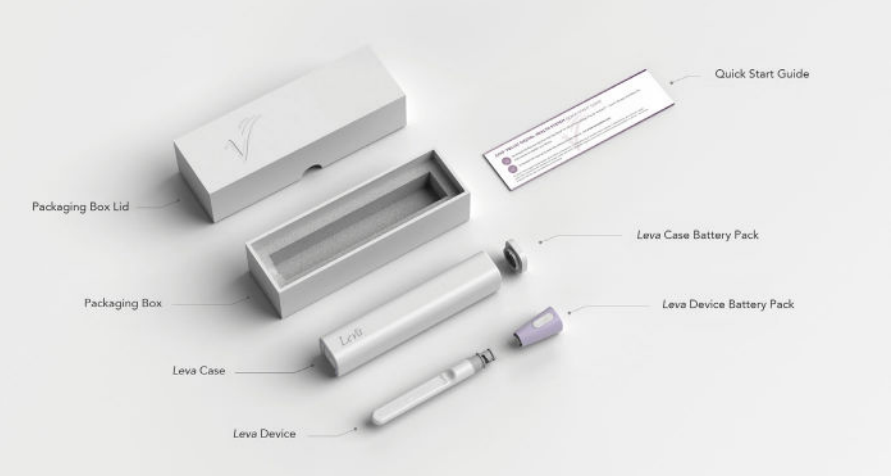


Figure 2. Packaging and Components of the *Leva* Pelvic Health System

The *Leva* software guides the user through a 2½-minute training regimen that is completed in the standing position. Each training session consists of five alternating 15-second periods of PFM contraction and relaxation. A visual display of the motion produced with each PFM contraction is depicted (Figure 3). The patient receives information about their ability to lift and hold the PFM contraction, as well as to relax between each repetition. Patients are instructed to complete supervised PFMT using the *Leva* Pelvic Health System twice daily for up to 12 weeks and may continue to use as desired or as directed by their clinician for up to six months.

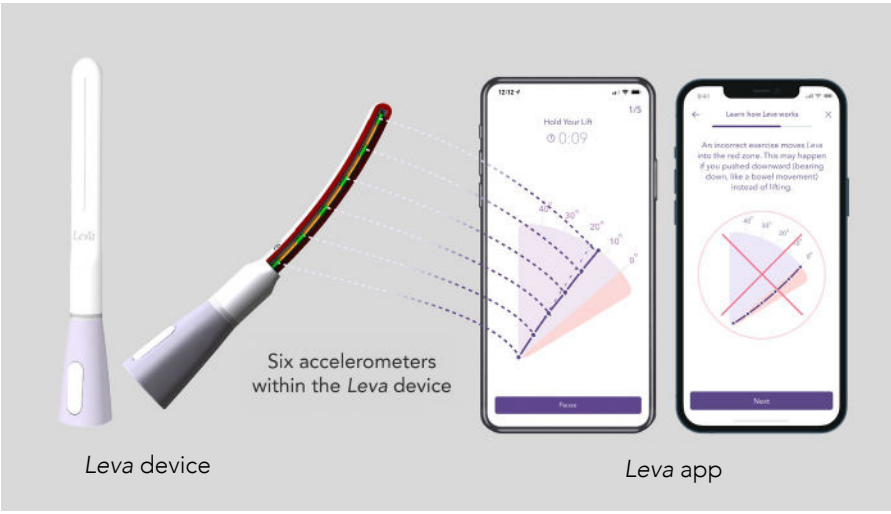


Figure 3. Motion-Based Mechanism of Action of the *Leva* Pelvic Health System

Evidence of Impact on Patients with Urinary Incontinence

Axena Health, Inc. has completed multiple clinical studies, including a randomized controlled trial with long-term follow-up and real-world evidence analyses examining outcomes and effectiveness of the *Leva* Pelvic Health System in the treatment of female urinary incontinence. Study details and key findings are summarized in Table 3. Details for select publications are provided on the following pages. No device-related serious adverse events were reported in any clinical studies.

Table 3. Research in patients with urinary incontinence

Study Description	Population	Key Findings	Related Publications
Pivotal RCT: 8-week results	**299 women** with Stress or Mixed UI: 143 *Leva* 156 Controls	· Statistically and clinically significant symptom improvement at 8-weeks in favor of *Leva* · *Leva* group experienced significantly greater reduction in SUI episodes, greater symptom improvement on Urogenital Distress Inventory (UDI-6) survey, and greater Patient Global Impression of improvement	Weinstein et al., *Obstetrics & Gynecology* 2022[1] Weinstein et al., *Contemp Clin Trials.* 2021 (Methods)[52]
Pivotal RCT: Longitudinal analysis at 12- and 24-months	**231 women** with Stress or Mixed UI: 101 *Leva* 130 Controls	· Follow-up at 12 months for 96% of pivotal RCT participants · Follow-up at 24 months for 77% of pivotal RCT participants · Twice greater odds of symptom improvement with *Leva* vs. control	Weinstein et al., *Obstetrics & Gynecology* 2023[2] Weinstein et al., *Int Urogynecol J* 2024[3]
Real world evidence: Observational study of commercial *Leva* patients	**947 women** with Stress, Mixed, Urgency UI or OAB	· 74% achieved clinically meaningful improvement in UI symptoms · Statistically and clinically significant improvement regardless of age, BMI, or UI subtype	Hall et al., *JMIR Formative Research* 2024[5]

Study Description	Population	Key Findings	Related Publications
Retrospective review of real-world *Leva* patients	**265 women** with Stress, Mixed, Urgency UI or OAB	· Demonstrates effectiveness in reducing UI symptoms in a real-world setting · Statistically and clinically significant symptom improvement at 8 weeks across all UI subtypes and regardless of age or BMI	Keyser et al., *Int Urogynecol J* 2022[4]
Multi-center pilot RCT	**61 women** with Stress or Mixed UI: 29 *Leva* 32 Controls	· *Leva* group experienced 70% reduction in stress UI episodes at 8-weeks and reported significant improvement in symptoms and quality-of-life	Weinstein et al., *Female Pelvic Med Reconstr Surg.* 2021[53]
Single-arm, proof-of-concept study	**23 women** with Stress or Mixed UI	· 87% symptom improvement · Symptom improvement correlated with gains in PFM performance	Rosenblatt et al., *Neurourol Urodyn.* 2019[54]

Pivotal Randomized Controlled Trial: 8 Week Results

Digital Therapeutic Device for Urinary Incontinence: A Randomized Controlled Trial

Obstetrics & Gynecology. Volume 139. Issue 4. April 2022.

The objective of this trial was to compare the efficacy and safety of PFMT facilitated by *Leva* with standard care in the treatment of stress or stress-dominant mixed UI. A prospective, 8-week, remotely executed trial was conducted. After on-line recruitment and screening, 363 women were randomized. Data was available for 156 women in the control group that received a home PFMT program using written/video instructions and 143 women in the intervention group that received the *Leva* device to guide PFMT. Symptom improvement was measured by change in scores on the Urogenital Distress Inventory (UDI-6),[50,51] the number of stress UI episodes on a 3-day bladder diary, and the Patient Global Impression of Improvement (PGI-I)[55] survey.

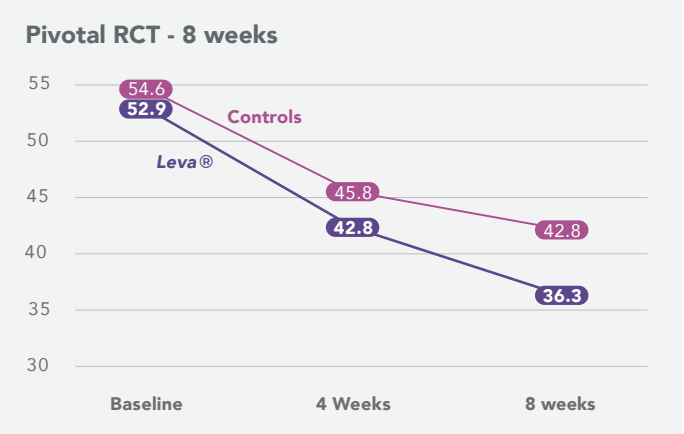
Key Findings

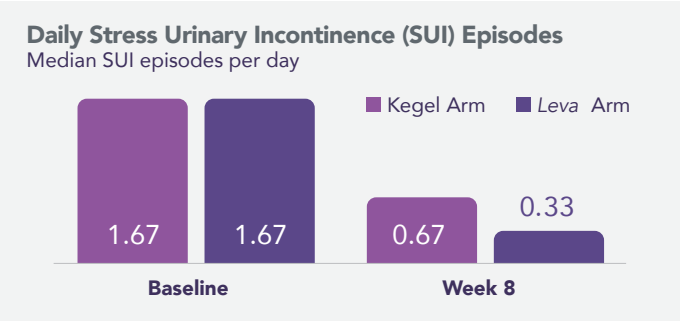
- Use of *Leva* yields superior results compared to a standard home PFMT program
  - Significantly greater improvement in UDI-6 scores (18.8 vs. 14.7 points, p=0.01)
    - *Leva* users met or exceeded the UDI-6 Minimum Important Difference[56] at 4 weeks and again at 8 weeks, indicating continued clinically meaningful symptom improvement across the study period.
  - Significantly greater reduction in median Stress UI episodes on 3-day bladder diary
    - *Leva* users reported 78% fewer Stress UI episodes from baseline to 8 weeks
  - Twice greater odds of improvement among *Leva* users compared to control group
    - Proportion of subjects who indicated symptoms were 'much better' or 'very much better' on PGI-I at 8 weeks: 44.1% *Leva* vs. 28.9% controls, OR 1.9, 95% CI 1.2-3.2
- No device-related severe adverse events among enrolled subjects.

Conclusions

PFMT guided by *Leva* results in statistically and clinically significant improvement in UI symptoms compared to a standard PFMT program of written/verbal instructions at 8-weeks. The remote trial design demonstrates that use of *Leva* can deliver safe and efficacious at-home treatment for UI.

Study Population	
Mean Age	51.7 years (range 18-78)
Mean BMI	31.7 kg/m2 (Class 1 Obesity)
Racial Diversity	20% non-white
Ethnic Diversity	10% Hispanic
Pregnancy History	88% ≥1 pregnancy
Menopausal status	54% post-menopause





Pivotal Randomized Controlled Trial: Longitudinal Analysis At 12 & 24 Months

Digital Therapeutic Device for Urinary Incontinence: A Longitudinal Analysis at 6 and 12 Months.
Obstetrics & Gynecology. Volume 141. Issue 1. January 2022.

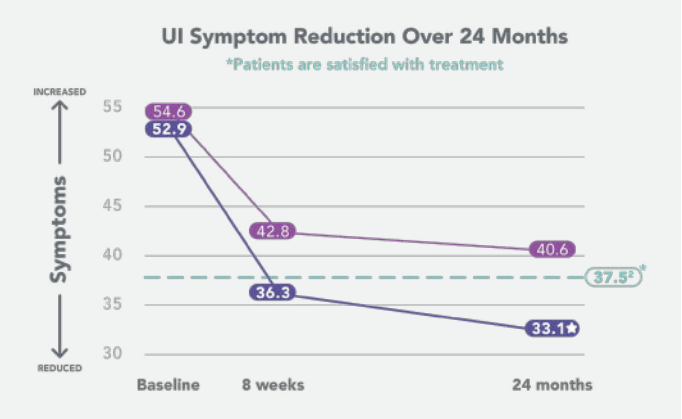
A Motion-Based Device Urinary Incontinence Treatment: Longitudinal Analysis at 18 and 24 Months.
International Urogynecology Journal. Volume 35. Issue 4. April 2024.

The objective of these trials was to evaluate the long-term efficacy of an 8-week PFMT program facilitated by *Leva* compared with a standard home program in the treatment of stress or stress-dominant mixed UI. After 8 weeks, participants were not asked to continue treatment. Long-term follow-up data was collected every six months up to two years and included Urogenital Distress Inventory (UDI-6) and Patient Global Impression of Improvement (PGI-I) survey scores – each validated to assess change in UI symptoms with treatment.[50,51,55,56] Of 299 participants analyzed at 8 weeks, 286 (96%) returned 6- and 12-month data, and 231 (77%) provided 18- and 24- month data.

Key Findings

- An 8-week PFMT program facilitated by *Leva* yields superior and durable results at 24-months, compared to an 8-week standard home PFMT program.
  - Significantly greater improvement in UDI-6 scores from baseline to 24-months (21.1 vs. 14.7 points, p=0.04)
  - *Leva* users met or exceeded the Minimum Important Difference at 8-weeks, and this was maintained at 24-months.
- UDI-6 scores among *Leva* users fell below the Patient Acceptable Symptom State (PASS) threshold score of 37.5 points.[57] Individuals who score below this threshold are likely to consider their symptoms well-controlled and no longer seek treatment.
- PGI-I improved significantly more in the *Leva* group.
  - At 12-months, *Leva* users were 2.5 times more likely to report symptom improvement: OR 2.45, 95% CI 1.49-4.00
  - At 24 months, *Leva* users were 2 times more likely to report symptom improvement: OR 1.95, 95% CI 1.08, 3.57

Study Population	
Mean Age	51.7 years (range 18-78)
Mean BMI	31.8 kg/m2 (Class 1 Obesity)
Racial Diversity	20% non-white
Ethnic Diversity	8.7% Hispanic
Median Parity	2 pregnancies
Menopausal status	55% post-menopause



- Most did not continue to use the *Leva* device after the 8-week program, thus, indicating that an initial course of treatment resulted in persistent symptom improvement at two years.

Conclusions

An initial program of PFMT guided by *Leva* results in statistically and clinically significant improvement in UI symptoms compared to a standard PFMT program of written/verbal instructions. These results are durable for at least 24 months. Ongoing use of the *Leva* device was not required to maintain results after the initial treatment.

Real World Evidence: Observational Study Of Commercial *Leva* Users

Real-World Evidence from a Digital Health Treatment Program for Female Urinary Incontinence: Observational Study of Outcomes Following User-Centered Product Design
JMIR Formative Research. Volume 8. Issue e58551. June 2024.

The objective of this study was to evaluate effectiveness and safety of the *Leva* Pelvic Health System for the treatment of stress, urgency, and mixed urinary incontinence (UI) among a cohort of real-world patients prescribed *Leva* to facilitate supervised PFMT. This retrospective cohort study analyzed commercial user data between January 1, 2022 – June 30, 2023, and included 947 women with UI who completed baseline and at least one follow-up Urogenital Distress Inventory (UDI-6) survey. Effectiveness was evaluated in three ways: proportion of patients who met the UDI-6 Minimum Important Difference,[56] proportion of patient who met the UDI-6 Patient Acceptable Symptom State (PASS) threshold score of 37.5 points,[57] and proportion of patients who reported improvement on the Patient Global Impressions of Improvement (PGI-I).[55]

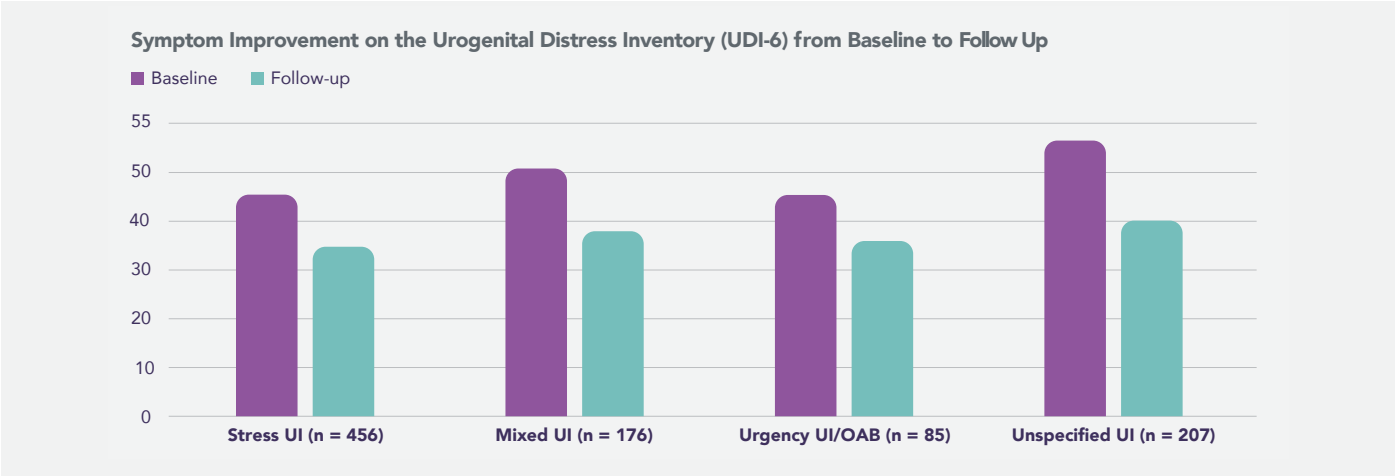
Key Findings

- Mean baseline UDI-6 score was 46.8 points, and mean UDI-6 score change from baseline to follow-up was 11.3 points ($p < 0.001$).
- 74% of users (697/947) experienced clinically significant improvement:
  - 58.4% met UDI-6 Minimum Important Difference
  - 60.6% met the PASS threshold score. Those who score below this threshold are likely to consider their symptoms well-controlled and no longer seek treatment.
  - Of 651 PGI-I responses, 77% (501/651) reported improvement
- Improvement in UDI-6 scores was observed across users, regardless of age, BMI, and UI sub-type, and symptom improvement was similar across these categories.

Study Population	
Mean Age	51 years
Mean BMI	28.3 kg/m2 (Overweight)
Racial Diversity	24% Non-white
Ethnic Diversity	6% Hispanic

Conclusions

This study provides real-world evidence supporting the effectiveness of the *Leva* Pelvic Health System to treat stress, mixed and urgency UI. A supervised PFMT program guided by *Leva* yields statistically and clinically significant improvement in UI symptoms across age and BMI categories and UI subtypes. Study results align with effectiveness of supervised PFMT reported by systematic reviews and meta-analyses.[36]



Health Economics and Outcomes Research

Health Economics and Outcomes Research

In May 2025, the *Journal of Medical Economics* published a peer-reviewed budget impact model of the *Leva* Pelvic Health System. The publication demonstrated an average of $1.07 per-member-per-month (PMPM) cost savings to health plans when the *Leva* system was used as a first-line treatment for female urinary incontinence compared to current clinical practice (CCP).[58]

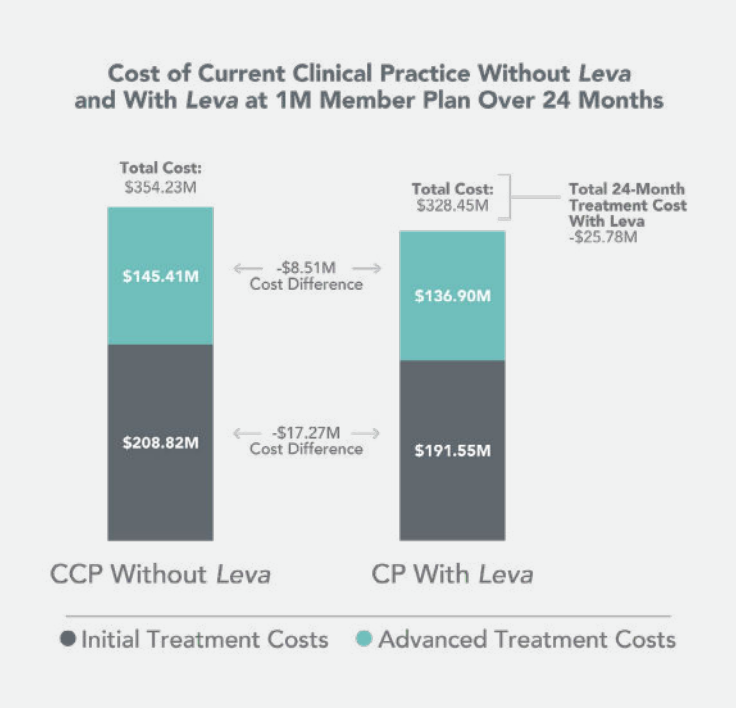
The model compared 24-month costs associated with first-line pelvic floor muscle training (PFMT) in women seeking UI treatment in two cohorts: 85% receiving first-line CCP treatment and 15% receiving the CP with *Leva*, compared to all patients receiving CCP treatment. The analysis was based on a representative United States commercial health plan with 1 million members.

Key results from the analysis include:

- In a United States commercial health plan with 1 million members, 334,191 were adult women, of whom 31,438 (9.4%) were treated for UI over 24 months.
- The total estimated 24-month cost per treated patient was $10,447 for the 15% receiving CP with *Leva* versus $11,267 for the 85% receiving first-line CCP treatment, respectively. The total cost for the *Leva* group ($10,447) includes the $2,100 intervention cost of *Leva*.
- This resulted in total projected savings of over $25.7 million over 24 months, or $1.07 PMPM.

The results show that patients who used *Leva* experienced lower utilization of high-cost and invasive treatments, such as medications or surgery, leading to measurable reductions in total medical spend.

Medical spending per treated patient and per-member-per-month were calculated by summing 24-month UI treatment costs comparing CCP to CP with *Leva*. The treatment pathway was developed based on published guidelines and literature to obtain estimates of success and complications. Commercial payor costs were estimated by applying a 1.50× multiplier to published Medicare costs based on Congressional Budget Office data for Hospital and Physician Services.



Market Adoption

Demonstrated Commercial Success and Clinical Validation

Since its FDA clearance, the *Leva* Pelvic Health System has achieved significant market penetration and clinical validation, demonstrating strong adoption across key stakeholder groups including payors, healthcare providers, patients, and leading medical organizations. This widespread acceptance underscores both the clinical value and real-world effectiveness of the *Leva* system in addressing the substantial unmet need in female urinary incontinence treatment.

Clinical Evidence Foundation

The market adoption of *Leva* is built upon a robust foundation of clinical evidence:

11 Peer-Reviewed Publications
Extensive scientific validation through peer-reviewed literature

Data from Over 1,200 Women
Large-scale evidence base demonstrating effectiveness across diverse patient populations

Continued Scientific Support
Ongoing research and real-world evidence generation supporting effectiveness

Payor Coverage and Patient Access

The *Leva* Pelvic Health System has secured broad reimbursement coverage, making this innovative treatment accessible to millions of women across the United States:

- **30+ Million Covered Lives** through major insurance providers including:
  - Cigna
  - Highmark Blue Cross Blue Shield
  - Geisinger
  - Blue Cross Blue Shield of North Dakota
  - Veterans' Health Administration (VHA)
  - Several Regional Blues Plans with established medical necessity
- **Geographic Diversity:** Coverage spans national and regional plans, ensuring broad access

This extensive payor adoption reflects recognition of *Leva*'s clinical effectiveness, economic value, and ability to address gaps in the current care pathway.

Provider Adoption and Utilization

Healthcare providers across multiple specialties have embraced the *Leva* Pelvic Health System as a valuable tool in their treatment protocol:

Provider Metrics

- **Nearly 3,000 Prescribing Providers:** Healthcare providers nationwide have incorporated *Leva* into their clinical practice
- **Almost 25,000 Prescriptions:** Demonstrating sustained utilization and growing integration into clinical workflows
- **Multi-Specialty Adoption:** Prescribers span across:
  - Urogynecologists
  - Obstetrician-Gynecologists
  - Urologists
  - Primary Care Physicians
  - Advanced Practice Providers

Clinical Integration Success

The strong provider adoption indicates successful integration into clinical practice and recognition of *Leva*'s ability to:

- Deliver supervised PFMT in accordance with clinical guidelines
- Provide objective data on treatment outcomes
- Fill the gap in first-line treatment delivery
- Improve adherence to clinical practice guidelines endorsed by professional societies (i.e., ACOG, AUGS, AUA, AAFP)

Medical Society Support and Health System Validation

Leva has received strong support from leading medical organizations and prestigious health systems, further validating its clinical utility:

Professional Society Recognition

- **American Urogynecologic Society (AUGS):** Support from the leading subspecialty organization
- **American College of Obstetricians and Gynecologists (ACOG):** Support from the premier women's health organization
- **National Association For Continence (NAFC):** Recognition from the leading patient advocacy organization

Health System Adoption

- **Mayo Clinic:** Recent strategic collaboration with one of the nation's most prestigious health systems
- **Growing Health System Integration:** Adoption by leading academic and community health systems nationwide

This widespread support reflect recognition of *Leva*'s alignment with evidence-based care and its potential to improve patient outcomes.

Patient Utilization and Safety

The ultimate measure of success is demonstrated through real-world patient outcomes:

- **Over 6,000 Women Treated:** As of May 2025, demonstrating strong patient acceptance
- **Zero Serious Device-Related Adverse Events:** Exceptional safety profile maintained across all users
- **Approximately 75% Adherence Rate:** Superior engagement compared to traditional unsupervised PFMT programs
- **Diverse Patient Population:** Success across various ages, BMI categories, and UI subtypes
- **Sustained Engagement:** High adherence throughout the full 12-week treatment period indicates strong patient satisfaction and perceived benefit

These metrics demonstrate that *Leva* successfully translates clinical trial efficacy into real-world effectiveness while maintaining an exemplary safety profile.

Market Impact

Leva has successfully established itself as a transformative solution within the urinary incontinence care pathway. Its market adoption highlights the potential of innovative, evidence-based technologies to address longstanding gaps in women's healthcare while delivering both clinical effectiveness and commercial success.

Robust clinical evidence
(11 publications,
1,200+ women studied)

Widespread provider adoption
(nearly 3,000 providers, almost
25,000 prescriptions)

Expanding payor coverage
(30+ million lives)

Exceptional safety profile
(zero serious adverse events)

Strong patient adherence
(>80%)

Support from leading medical organizations

Together, these milestones paint a clear picture of *Leva's* growing role in advancing care and meeting a significant unmet need in women's health.

More Information

Safety

There have been no device-related serious adverse events associated with the *Leva* Pelvic Health System since its launch in July 2020. *Leva* is well tolerated by patients. Few adverse events were reported by clinical trial participants (urinary tract infections: 1.7%; vaginal irritation: 2.7%). Among over 5,900 commercial users, the most common but rare minor adverse events were urinary tract infections (1.27%), skin irritation (1.18%) and lower back pain (1.07%).

The device is manufactured with Thermoplastic Elastomers (TPE) and has undergone bio-compatibility testing to minimize risks associated with allergic reaction to material. Patients are advised to contact their healthcare provider if they experience redness or swelling near the insertion area. Patients who experience irritation are recommended to use a small amount of water-based lubricant, at the tip of the wand to make insertion easier. Contact irritation can also occur when the skin contacts potentially irritating materials, such as soap or cleaners. Patients are advised to clean the wand with mild soap and water only and to avoid alcohol or other chemical cleaners.

Important Safety Information

Do not share the *Leva* system. *Leva* is a single-user medical device. Do not use the *Leva* Pelvic Health System while pregnant, or if you think you may be pregnant, unless authorized by your healthcare provider. Do not leave the *Leva* vaginal wand in your body for longer than necessary to complete the training session. Remove the vaginal wand after each training session. Do not use the *Leva* Pelvic Health System in any other place in your body. Do not have sexual intercourse while the vaginal wand is inserted. If you experience odor, fever, vomiting, diarrhea, any signs of infections or any flu-like symptoms, contact your doctor immediately. If you experience redness or swelling near the insertion area, or signs of an allergic reaction, contact your healthcare provider immediately. For a complete summary of the risks and instructions for the *Leva* System, see its Instructions for Use available at www.levacares.com. Treatment with the *Leva* Pelvic Health System is prescribed by your healthcare provider. This treatment is not for everyone. Please talk to your healthcare provider to see if it is right for you. Your healthcare provider should discuss all potential benefits and risks with you.

Patient Selection

The *Leva* Pelvic Health System is a prescription product indicated for female patients with a diagnosis of stress, mixed, or urgency UI, including Overactive Bladder. The *Leva* Pelvic Health System may be offered as first line treatment for these conditions or in conjunction with advanced treatments.

The *Leva* Pelvic Health System requires that patients can insert the intravaginal wand and stand independently for at least five minutes and is not suitable for use in a sitting or lying position. It also requires that users are cognitively intact and can operate a smartphone or tablet. Pregnant individuals should only use the *Leva* Pelvic Health System in consultation with their physician.

The *Leva* Pelvic Health System has proven effectiveness in community-dwelling, ambulatory, adult women across age, BMI, and UI subtype categories. Successful use has been observed in both clinical trial participants and among real-world patients, including women over 90 years of age and those who are overweight or obese.

Patient Testimonials

Patients who used the *Leva* Pelvic Health System provide perspective in their own words.

"It's easy to use and has been effective for me. It has prevented me from having to go through a surgical procedure." **Kimberly M, 66**

"Now I am able to wait longer between trips to the bathroom. I am having less urge incontinence and spasms. I am not wearing pads … I'm glad I used Leva because I am getting more control over my bladder symptoms. I am getting my life back." **JoAnn, 62**

"Since using Leva, I have had a reduction in nighttime bathroom visits, more ability to hold it,' and I can get away without wearing a liner." **Leva user, 67**

"I can now exercise with little or no bladder leakage. I can also enjoy long walks without the urgency to use the bathroom. I can shop without visiting every restroom!" **Karen B, 58**

"Now that I used Leva, I can play games that include a lot of movement with my children. I leave the house without a diaper bag. I don't go straight to the restroom when I arrive somewhere, 'just in case'." **Jamie S, 39**

Additional testimonials from both patients and health care providers may be found here.

Publications

Leva-related Publications:

1. Weinstein MM, Dunivan GC, Guaderrama NM, Richter HE. Impact of a Digital Therapeutic Device on Pelvic Floor Symptoms. *Urogynecology (Phila).* Published online March 17, 2025. doi:10.1097/SPV.0000000000001674

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11. Weinstein MM, Pulliam SJ, Keyser L, Richter HE. Use of a motion-based digital therapeutic in women with fecal incontinence: A pilot study. *Neurourol Urodyn.* 2022;41(1):475-481. doi:10.1002/nau.24854

Additional Publications:

12. McKinney JL, Keyser LE, Pulliam SJ, Ferzandi TR. Female Urinary Incontinence Evidence-Based Treatment Pathway: An Infographic for Shared Decision-Making. *J Womens Health (Larchmt).* 2022;31(3):341-346. doi:10.1089/jwh.2021.0266

13. McKinney JL, Datar M, Pan LC, Goss T, Keyser LE, Pulliam SJ. Retrospective claims analysis of physical therapy utilization among women with stress or mixed urinary incontinence. *Neurourol Urodyn.* 2022;41(4):918-925. doi:10.1002/nau.24913

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Posters & Conference Presentations:

American Urogynecologic Society PFD week October 2024

16. Eppinger A, Melamed A, Weinstein M Predicting Success in Women Choosing Firstline Treatment for Urinary Incontinence. (Full Oral #24)

Society for Urodynamics and Female Urology Winter Meeting – February 2024

17. Keyser L, McKinney J, Pulliam S, Weinstein M. A Technology-driven At-home Prescription Program for Urinary Incontinence: Retrospective Review of Real-World User Data (Poster NM039)

International Urogynecological Association - Annual Meeting 2023

18. Weinstein MM, Dunivan G, Guaderrama NM, Richter HE. 18- and 24-Month Follow-Up of a Randomized Controlled Trial Comparing 8 Weeks of Pelvic Floor Muscle Training Guided by a Digital Therapeutic Device versus Home Program. (Best Overall Abstract Presentation #001).

American Urogynecologic Society/International Urogynecological Association – AUGS/IUGA Scientific Meeting 2022

19. Weinstein MM, Dunivan G, Guaderrama NM, Richter HE. Digital Therapeutic Device for Urinary Incontinence: 6- and 12-Month Follow-up of a Randomized Controlled Trial (Short Oral #78).

20. Weinstein MM, Dunivan G, Guaderrama NM, Richter HE. Pelvic Floor Excursion and Endurance in Response to Pelvic Floor Muscle Training Using a Digital Therapeutic Device (Short Oral #103).

21. Pennycuff J, Pulliam S, McKinney J, Iglesia C. A Pilot Study of Home-Based Pelvic Muscle Training for Vaginal Symptoms Among Survivors of Breast Cancer (Short Oral #183).

22. Keyser LE, McKinney JL, Pulliam SJ, Weinstein MM. A Digital Health Program for Treatment of Urinary Incontinence: Retrospective Review of Real-World User Data (Poster #499).

23. Martin L, Abramowitch S, Rostaminia G. Multimodal Measurement of Vaginal Shape during Squeeze and Strain in Nulliparous Women (Poster #457).

24. Published: Abstracts, Female Pelvic Medicine & Reconstructive Surgery: June 2022 - Volume 28 - Issue 6S - p S1-S285. doi: 10.1097/SPV.0000000000001202

American College of Obstetricians & Gynecologists – ACOG Annual Meeting 2021

25. Weinstein MM, Pulliam SJ, Richter HE. Vaginal Motion-based Biofeedback for Treatment of Fecal Incontinence in Women. (Non-oral poster)

Professional Society for Health Economics and Outcomes Research – ISPOR 2020

26. Datar M, Pan LC, Pulliam S, McKinney J, Sweeney L, Goss TF. PUK18 Retrospective Assessment of Healthcare Resource Use and Costs in Patients with Stress/Mixed Urinary Incontinence. *Value Heal*. 2020;23:S380. doi:10.1016/j.jval.2020.04.1475 (Non-oral poster)

Society of Gynecologic Surgeons – SGS 2020 Webinar Program

27. Pulliam S, Datar M, Goss T, Pan L, Wu JM. 105: Retrospective assessment of the incremental disease burden of urinary incontinence. A*m J Obstet Gynecol*. 2020;222:S834. https://doi.org/10.1016/j.ajog.2019.12.145 (Non-oral poster)

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