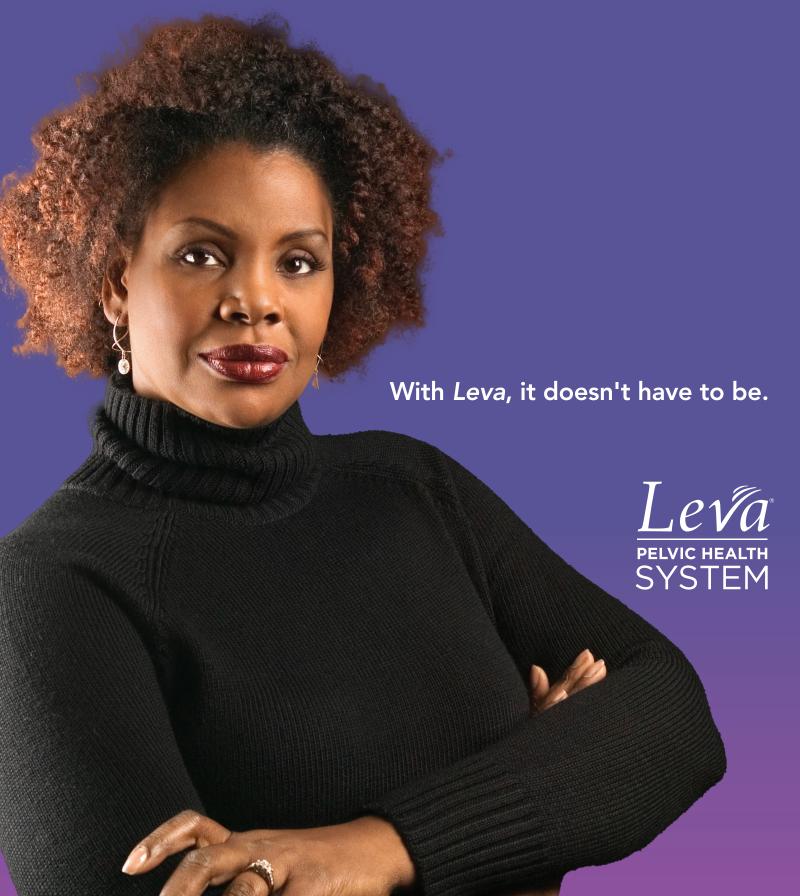
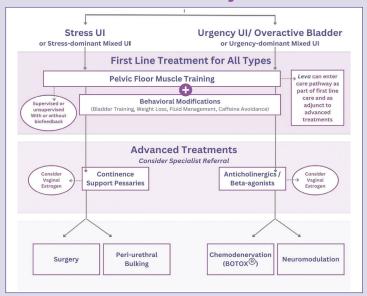
# Urinary Incontinence (UI) is a serious challenge for women and providers

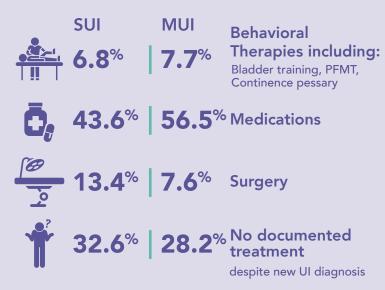


### 11 million women seek treatment for Ul

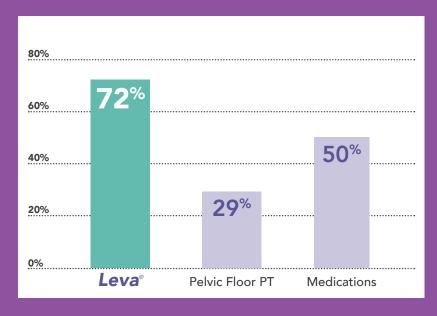
#### Female Urinary Incontinence Care Pathway<sup>3</sup>



## Documented First Treatment for Patients Seeking Care for Ul



# Typical patient adherence to common treatment options



#### Leva Pelvic Health System

Of women who use Leva as directed,
72% device-reported adherence at one month<sup>5</sup>

#### Pelvic Floor PT

 Of women who start PFPT, only 29% complete a course of care defined as 3 visits<sup>6</sup>

#### Medications

Of women taking medications as prescribed,
50% discontinue use within five months<sup>7</sup>

## Now there's a serious solution to treat stress, mixed, and urgency UI

including overactive bladder (OAB)

Barriers to supervised PFMT:

Leva was developed to address these barriers and make first-line care accessible and scalable.

Limited number of PTs & long wait times

• Leva is at-home, individualized PFMT and can be used from anywhere

**Time constraints** 

• 2.5 minutes, 2x/day for 12 weeks

Internal exams

• Discreet, non-invasive, motion-based technology with visual guidance

Financial constraints

- Leva Women's Center manages benefits check, PAs and appeals
- National/regional insurance coverage; FSA/HSA eligible; payment plan options

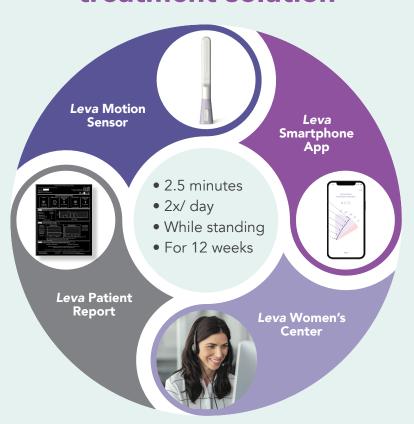
## Why supervised PFMT is recommended

Findings from an Overview of Cochrane Systematic Reviews:

"There is high certainty evidence that undertaking pelvic floor muscle training can cure symptoms and improve quality of life for all types of urinary incontinence."

"There is moderate or high certainty evidence that these pelvic floor muscle exercises work better if they are more intense, have more support from a health care professional, and are combined with strategies to support continued use." 8

## Why Leva is a first-line treatment solution







### Evidence-based, proven improvement

#### Clinical data for SUI and MUI published in the Green Journal

- Results in as early as 4 weeks9
- Decrease in leaking episodes from about 2 leaks per day to about 2 leaks per week<sup>9</sup>
- Improvement regardless of UI symptom severity<sup>9</sup>
- Durability for at least a year<sup>10</sup>

### Peer-reviewed real-world evidence study of Leva® users published in the International Urogynecology Journal

- Leva is effective for stress, mixed, and urgency UI (including overactive bladder)<sup>5</sup>
- 78% of Leva users see significant symptom relief<sup>5</sup> which is comparable to supervised PFMT in Cochrane Reviews<sup>11</sup>
- 72% device-reported adherence at 4 weeks<sup>5</sup>

### Serious consequences for the 78M' women with UI

(if left untreated)

UI symptoms may worsen over time<sup>12</sup>

Women with prior UI have 25x greater odds of UI recurrence<sup>13</sup> Negative impact on quality of life, physical function, and cognitive performance and associations with obesity, depression, and anxiety.<sup>14-18</sup>

Provider Support: (866) 657-5382 • www.levatherapy.com

**Important Indication and Other Information for the** *Leva* **Pelvic Health System:** The *Leva* Pelvic Health System is intended for treatment of stress, mixed and mild to moderate urgency urinary incontinence (including overactive bladder), treatment of chronic fecal incontinence (>3-month uncontrolled passage of feces), and strengthening pelvic floor muscles in women. Talk to your provider to see if the *Leva* System is right for you. Do not use the *Leva* System while pregnant, or if you think you may be pregnant, unless authorized by your doctor. For a complete summary of the risks and instructions for the *Leva* System, see its Instructions for Use available at **www.levatherapy.com**.

Sources: 1. Patel UJ, Godecker AL, Giles DL, Brown HW. Updated Prevalence of Urinary Incontinence in Women: 2015-2018 National Population-Based Survey Data. Female Pelvic Med Reconstr Surg. 2022 Apr 1;28(4):181-187. doi: 10.1097/ SPV.0000000000001127. Epub 2022 Jan 12. PMID: 35030139. 2. Waetjen LE (2018) Factors associated with reasons incontinent midlife women report for not seeking urinary incontinence treatment over 9 years across the menopausal transition. Menopause. 2018;25(1):29-37. 3. 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. 4. Pan LC, Datar M, McKinney JL, Keyser LE, Goss TF, Pulliam SJ. Adherence to professional society guidelines among women with stress or mixed urinary incontinence. Neurourol Urodyn. 2022;41(6):1489-1497. doi:10.1002/nau.24986. 5. Keyser LE, McKinney JL, Pulliam SJ, Weinstein MM. A digital health program for treatment of urinary incontinence: retrospective review of real-world user data [published correction appears in Int Urogynecol J. 2023 Jun 27;:]. Int Urogynecol J. 2023;34(5):1083-1089. doi:10.1007/s00192-022-05321-3. 6. Shannon MB, Attendance at Prescribed Pelvic Floor Physical Therapy in a Diverse, Urban Urogynecology Population. PM&R. 2018;10(6):601-606. 7. Yeowell G, Smith P, Nazir J, Hakimi Z, Siddiqui E, Fatoye F. Real-world persistence and adherence to oral antimuscarinics and mirabegron in patients with overactive bladder (OAB): a systematic literature review BMJ Open. 2018;8(11). 8. Todhunter-Brown A, Hazelton C, Campbell P, Elders A, Hagen S, McClurg D. Conservative interventions for treating urinary incontinence in women: an Overview of Cochrane systematic reviews. Cochrane Database Syst Rev. 2022;9(9):CD012337. Published 2022 Sep 2. doi:10.1002/14651858.CD012337.pub2. 9. Weinstein, et al. Digital Therapeutic Device for Urinary Incontinence, Obstetrics & Gynecology (April 2022). 10. Weinstein, et al. Digital ice for Urinary Incontinence, Obstetrics & Gynecology (April 2022). Incontinence: A Longitudinal Analysis at 6 and 12 Months. Obstet Gynecol. 2023 Jan. 11. Dumoulin C, Cacciari LP, Hay-Smith EJC. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. Cochrane Database Syst Rev. 2018;10(10):CD005654. Published 2018 Oct 4. doi:10.1002/14651858.CD005654.pub4. 12. Minassian VA, Hagan KA, Erekson EA. The natural history of urinary incontinence in blurses' Health Studies. Am J Obs Gynecol. 2020;222(2):163.e1-163.e8. doi:10.1016/j.ajog.2019.08.023. 13. Komesu YM, Schrader RM, Ketai LH, Rogers RG, Dunivan GC. Epidemiology of Mixed, Stress & Urgency Urinary Incontinence in Mid-Aged/Older Women: Importance of Incontinence History. Int Urogynecol J. 2016;27(5):763-772. doi:10.1007/s00192-015-2888-1.Epidemiology. 14. Mendes A, Hoga L, Gonçalves B, Silva P, Pereira P. Adult women's experiences of urinary incontinence: a systematic review of qualitative evidence. JBI Database System Rev Implement Rep. 2017;15(5):1350-1408. doi:10.11124/JBISRIR-2017-003389. 15. Ca Correa L, Pirkle CM, Vafaei A, Curcio CL, Câmara SM. Urinary incontinence is associated with physical performance decline in community-dwelling older women: results from the International Mobility in Aging Study (IMIAS). doi:10.1177/0898264318799223. 16. Lussier M, Renaud M, Chiva-Razavi S, Bherer L, Dumoulin C. Are stress and mixed urinary incontinence associated with impaired executive control in community-dwelling older women?. J Clin Exp Neuropsychol. 2013;35(5):445-454. doi:10.1080/13803395.2013.789483. 17. Subak LL, Richter HE, Hunskaar S. Obesity and urinary incontinence: epidemiology and clinical research update. J Urol. 2009;182(6 Suppl):S2-S7. doi:10.1016/j.juro.2009.08.071. 18. Cheng S, Lin D, Hu T, et al. Association of urinary incontinence and depression or anxiety: a meta-analysis J Int Med Res. 2020;48(6):300060520931348. doi:10.1177/0300060520931348.

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