

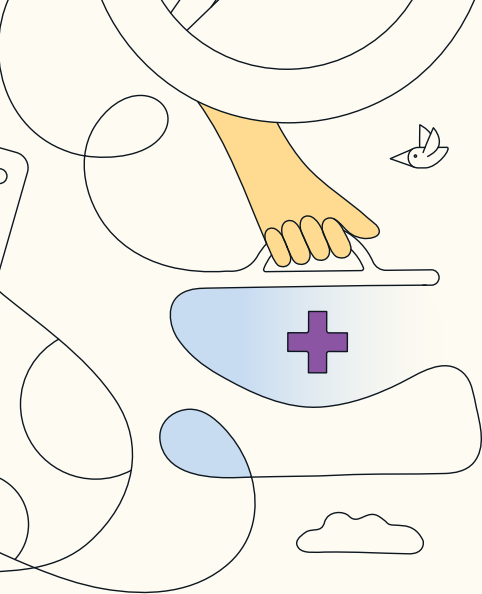


# STARTING THE CONVERSATION

The *leva*® Virtual Housecall.  
A personalized and empowering approach  
to treating urinary incontinence.

*leva*

Digital Therapeutic System



# MANY WOMEN WHO EXPERIENCE URINARY INCONTINENCE (UI) DON'T SEEK CARE<sup>1\*</sup>

## The *leva*<sup>®</sup> Virtual Housecall can help

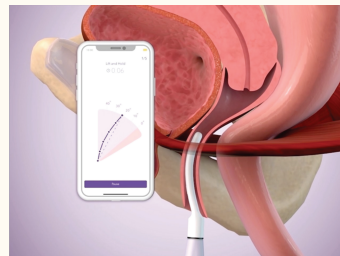
Renovia developed the *leva* Virtual Housecall to help you screen and diagnose UI in women via telemedicine. If treatment is appropriate, the ***leva* Digital Therapeutic System**, is an at-home treatment to support first-line care for UI. The System comprises the *leva* Motion Sensor powered by Accelerometer6™ technology, the *leva* app, and personal coaching from the Renovia Women's Center (RWC).

\* Of 1339 women who reported UI from baseline through visit 9 (data collected annually 1995-2005) and answered the treatment seeking questions, 814 (61%) reported they did not seek treatment for UI from a health care professional during follow up.

1. Waetjen LE, Xing G, Johnson WO, Melnikow J, Gold EB; Study of Women's Health Across the Nation (SWAN). 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.

## How Pelvic Floor Muscle Training with *leva*® Digital Therapeutic System can help address the problem

Pelvic Floor Muscle Training (PFMT) is a recommended first-line, conservative therapy for Stress, Urgency, and Mixed UI.<sup>2,3,4</sup> In a study of 325 women, 75% of women did not do their pelvic floor muscle exercises — and of those who did perform them, fewer than 25% performed them adequately.<sup>5†</sup>



PFMT with the *leva* Motion Sensor, powered by Accelerometer<sup>6</sup> technology, can help address this problem through measurement and tracking. Sensitive motion sensors measure movement when a woman contracts her pelvic floor muscles, an action that lifts the bladder neck and compresses the urethra against the pubic bone. The *leva* app provides her with visual real-time feedback, records data usage, and tracks self-reported symptoms to help women understand their progress over time.

### Personalized coaching with the Renovia Women's Center

Once you prescribe *leva*, a RWC Educator will contact your patient to complete their purchase. In addition, an RWC Coach will assist her in setting goals and following the training process. This personal support is an included part of the *leva* Digital Therapeutic System.

† n=325 women, averaging 57.8 years of age. All patients were presenting for evaluation of pelvic floor complaint and had one or more pelvic floor disorders.

2. Urinary Incontinence in Women. Practice Bulletin No. 155. American College of Obstetricians and Gynecologists. Obstet Gynecol 2015; 126:e66-81. 3. Qaseem A, Dallas P, Forcica 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. Hersh L, Salzman B. Clinical Management of Urinary Incontinence In Women [published correction appears in Am Fam Physician. 2013 Oct 1;88(7):427]. Am Fam Physician. 2013;87(9):634-640. 5. Moen MD, Noone MB, Vassallo BJ, Elser DM. Pelvic floor muscle function in women presenting with pelvic floor disorders. Int Urogynecol J. 2009;20(7):843-846.



## LET'S GET STARTED

To help you reach out to your patients and initiate *leva* Virtual Housecalls, Renovia has created *leva* Patient Engagement resources, a set of tools to help you:

- Screen for UI in your patient population, inform patients that your practice offers *leva*, and invite them to schedule a *leva* Virtual Housecall.
- Conduct the *leva* Virtual Housecall with patients.
- Provide patients with additional information about *leva*. Provide follow-up patient care.
- Announce via social and traditional media that your practice offers *leva*.

To access these tools, go to [knowleva.com/resources](https://knowleva.com/resources), where you can download and customize them for your practice.

# YOUR TOOLS

## Patient Letter

Send this letter to inform patients that you can screen for UI, discuss its treatment and prescribe the *leva* Digital Therapeutic System via a *leva* Virtual Housecall. This letter is in Word format so you can copy and paste its text into an email, or print it to send via conventional mail. Sample enclosed.

## Medical Order Form

Use to prescribe the *leva* Digital Therapeutic System for patients. Sample enclosed.

## Patient Brochure

Send to patients to provide more information about urinary incontinence and how pelvic floor muscle training with the *leva* Digital Therapeutic System works. Sample enclosed.

## Housecall Discussion Ideas

A script which includes key discussion points to help you conduct a *leva* Virtual Housecall.

## Care Pathway

A tool for discussion of the treatment options for UI and the role played by pelvic floor muscle training.



## Screening Tools

Standardized and validated tools are recommended for the systematic screening of UI in women. These tools are intended to simplify and facilitate the screening process:<sup>6</sup>

### 3 Incontinence Questionnaire (3IQ) Screener<sup>7</sup>

A standardized and validated tool for UI screening, which can be used at the beginning of a *Ileva* Virtual Housecall.

### Michigan Incontinence Symptom Index (MISI)<sup>8</sup>

A validated tool that was designed for use as a clinical aid for UI in women. The MISI addresses severity and bother of UI and describes total and subdomain Minimally Important Difference to reflect change over time.

## Press Release

Send to local news outlets to educate the community about this condition and to announce that your practice can prescribe the *Ileva* Digital Therapeutic System to treat UI in women. Provided to you in Word format so you can personalize it with your practice name, then email to local news outlets or print to send via conventional mail. Sample enclosed.

## Healthcare Provider Website Content

Articles, informational text, images, and videos you can put on your practice's website to educate patients about UI and how the *Ileva* Digital Therapeutic System is used to treat it.

6. Nelson HD, Cantor A, Pappas M, Miller L. Screening for urinary incontinence in women: a systematic review for the Women's Preventive Services Initiative. *Annals of Internal Medicine*. 2018 Sep 4;169(5):311-9. 7. Brown JS, Bradley CS, Subak LL, et al. The sensitivity and specificity of a simple test to distinguish between urge and stress urinary incontinence. *Ann Intern Med*. 2006;144(10):715-723. 8. Suskind AM, Dunn RL, Morgan DM, DeLancey JO, McGuire EJ, Wei JT. The Michigan Incontinence Symptom Index (M-ISI): a clinical measure for type, severity, and bother related to urinary incontinence. *Neurourol Urodyn*. 2014;33(7):1128-1134.

## Social Media Content

Text and images you can use to announce via social media that your practice can prescribe the *leva* Digital Therapeutic System and invite patients to make an appointment for *leva* Virtual Housecall.

## And More

We'll be updating the Resources Page, so check back for additional tools and clinical information.

**For more information about these resources, contact your representative.**

The *leva*® Digital Therapeutic System is intended for: (i) strengthening of the pelvic floor muscles; and (ii) 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. This product interacts with the user via smartphone technology.

Important Safety Information for *leva*: Do not use the *leva* Digital Therapeutic System while pregnant, or if you think you may be pregnant, unless authorized by your doctor. Do not leave *leva* in your body for longer than necessary to complete the training session. Do not use the *leva* Digital Therapeutic System in any other place in your body or have sexual intercourse while it is inserted. If you experience odor, fever, diarrhea, any signs of infection, or of an allergic reaction, contact your healthcare provider immediately. For a complete summary of the risks and instructions for the *leva* Digital Therapeutic System, see its Instructions for Use available at Renovia's website.

Treatment with the *leva* Digital Therapeutic System is available by prescription only. This treatment is not for everyone. Healthcare providers should discuss all potential benefits and risks of *leva* with patients.



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