

Dear \_\_\_\_\_ (personalized),

I'm writing you and all the women in our practice about a health issue that affects millions of women across the U.S. The issue is bothersome urinary leakage, also known as urinary incontinence.<sup>1</sup>

We know that this isn't an easy subject to discuss. Understandably, some women find it embarrassing. According to one study, **up to half of women with leakage problems do not seek care** because their doctor did not ask them about their symptoms.<sup>2\*</sup>

At [NAME OF PRACTICE], we're committed to addressing the diagnosis and treatment of urinary incontinence. **It is a serious health problem** that can negatively affect your quality of life and may lead to severe medical conditions. The good news is that new treatment options may eliminate or reduce symptoms without the need for costly surgery or long-term medication.

We're launching a new screening program for urinary incontinence treatment and would like you to consider these two questions:

- 1. During the last 3 months, have you leaked urine (even a small amount)?**
- 2. Were you bothered by these episodes?**

**If you answered YES to both questions**, we encourage you to schedule an appointment with our office. We'll walk you through a simple screening questionnaire, confirm a diagnosis, and then determine what treatment option would be best for you.

We can do a confidential assessment and make treatment recommendations through a telehealth appointment, also known as a virtual housecall, that's easy to set up. Of course, it's no problem if you'd prefer to come into the office.

**TAKE ACTION TODAY.** Call us at [XXX-XXX-XXXX] and one of our team members will book the appointment for you, so we can walk you through next steps and what to expect during this consultation.

There can be hope for women bothered by urinary leakage. If you're one of them, we look forward to talking to you soon!

[HCP NAME, NAME OF PRACTICE]

\*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. Wu JM, Hundley AF, Fulton RG, Myers ER. Forecasting the prevalence of pelvic floor disorders in U.S. Women: 2010 to 2050. *Obstet Gynecol.* 2009;114(6):1278-1283. 2. 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.

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* Digital Therapeutic System: Do not share the *leva* Digital Therapeutic System. *leva* is a single-user medical device. Do not use *leva* while pregnant, or if you think you may be pregnant, unless authorized by your doctor. Do not leave the probe in your body for longer than necessary to complete the training session. Remove the probe after each training session. Do not use *leva* in any other place in your body. Do not have sexual intercourse while the probe is inserted. If you experience odor, fever, vomiting, diarrhea, any signs of infections or any flu-like symptoms, contact your healthcare provider 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* Digital Therapeutic System, see its Instructions for Use available at Renovia's website.

Treatment with *leva* Digital Therapeutic 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.