



Dear Healthcare Provider,

Your patient has expressed interest in Elitone or Elitone URGE. We are providing this information to support a conversation regarding treatment options. Visit elitone.com/clinicians for additional information.

Elitone or Elitone URGE are **FDA-cleared external neuromodulation** devices used to contract and relax muscles to treat female urinary incontinence. They are painless, low-risk, high-benefit, clinically proven treatments that help women Regain Control, Regain Confidence®.



Stress urinary incontinence (SUI)

Non-vaginal toning of the pelvic floor muscles.

4sec muscle contraction + 2sec OAB relaxation

Alternative to:

- Passive Kegel coaches
- Vaginally inserted stimulation
- Surgery



Urge urinary incontinence (UUI) / OAB

Perineal-applied neuromodulation of the pudendal nerve

6sec for OAB relaxation

Alternative to:

- Anticholinergics and Beta3 Agonists
- Implanted sacral neuromodulation
- Peripheral neurostimulation (PTNS)

Ideal for:

- Busy moms
- Working women
- Postpartum care
- Aversion to vaginal devices
- Limited access to physical therapist
- Perform Kegels incorrectly
- Chronic skin irritation from wet pads
- Adjunct to physical therapy

Easy-to-Use

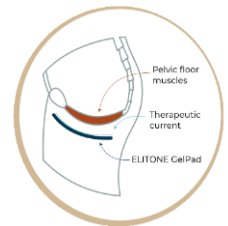
No training required. Use anywhere, anytime, while doing other tasks. This convenience drives compliance. **Use 4 times per week and see results in as few as 6 weeks.** It's easy, comfortable, and discreetly worn under clothes.



APPLY TO PERINEUM



ADJUST INTENSITY



WEAR FOR 20 MIN

Strong Clinical Results

Both ELITONE and ELITONE URGE demonstrated clinical efficacy in pragmatic clinical studies designed to reflect the “real world” use of home-use therapies.

>95%
reported fewer leaks

>70%
reduction in leaks

22 of 22
quality-of-life measures improved

85%
pad reduction with stress incontinence

<4%
returns for inefficacy

Prescribing and Insurance

A **prescription is not required**, and most women pay out of pocket, utilizing HSA/FSA or monthly payment options.

A prescription may help obtain insurance reimbursement under HCPCS code E0740 (Non-Implanted Pelvic Floor Electrical Stimulator). Typically, patients must have failed an ordered 4-week documented trial of pelvic muscle exercise training (i.e. Kegels). For more information see: elitone.com/reimbursement

Patient's Next Steps

1. Determine which ELITONE is right for you
2. Visit elitone.com/order to place order
3. ELITONE will be shipped directly to you
4. Begin treatment
5. Follow-up with your physician as necessary

clinicians@elitone.com, 978-435-4324

Manufactured by Elidah, Inc. Newtown, CT USA

Detailed Written Order

PATIENT INFORMATION

Patient Name: _____
Address: _____

Date of Birth: _____
Phone #: _____
Email: _____

Insurance Company: _____
Insured Name: _____

Group #/ID#: _____
Insurance Phone #: _____

Secondary Insurance: _____
Insured Name: _____

Group #/ID#: _____
Insurance Phone #: _____

MEDICAL NECESSITY

Diagnosis & ICD-10 CM Code:

Device Prescribed:

<input type="checkbox"/> N39.3 Stress Urinary Incontinence <input type="checkbox"/> N39.46 Mixed Incontinence	ELITONE Pelvic Floor Stimulator (HCPCS E0740), GelPads (HCPCS A4595)
<input type="checkbox"/> N39.41 Urge Urinary Incontinence	ELITONE URGE Pelvic Floor Stimulator (HCPCS E0740), GelPads (HCPCS A4595)

Has patient failed a structured 4 week *plan* of Pelvic Muscle Exercise (PME) training? Yes No

(REQUIRED: attach documentation of structured training showing no clinically significant improvement)**

Is patient cognitively intact? Yes No

Are the pelvic nerves intact? Yes No

Prognosis: Excellent Good Fair Poor

Date of most recent in-office visit: _____

PRESCRIPTION

I am prescribing the above device to decrease urinary leakage associated with urinary incontinence.

Length of Need: Lifetime (≥ 13 months) Other _____

Deliver To: Clinician's Facility Patient's Home*

Prescribing Physician Name: _____ NPI #: _____

Facility Address: _____

Phone #: _____ Fax #: _____

Physician Signature: _____ Date: _____

I certify that I am the physician identified in this form. I have reviewed all sections of the physician's written order. Any statement on my letterhead attached here to has been reviewed and signed by me. The patient's record contains supporting documentation which substantiates the utilization and medical necessity of the ELITONE device and physician notes will be provided to an authorized distributor upon request. I understand any falsification, omission or concealment of material fact may subject me to civil or criminal liability. *My above signature indicates my approval to ship the instrument to my patient's home and releases shipper from any liability from its use prior to proper instrument education and training.

Elidah, Inc., the maker of ELITONE, does not process insurance. Detailed Written Orders received by Elidah will be forwarded to a DME provider for processing. Elidah may maintain contact information to enable follow-up regarding completion of the order. Medical information is not retained by Elidah.