Dear FSA/HSA Provider,

According to Section 213(d) of the Internal Revenue Service Tax Code, an approved medical expense includes treatment (equipment and supplies, therapy equipment) affecting any function of the body.

The ELITONE device was FDA-cleared for use at-home, Over-the-Counter (FDA Owner/Operator Number: 10059852, Device Submission K183585). It is a pelvic floor muscle stimulator treatment for incontinence, which is a durable medical equipment (approved by CMS accordingly on March 7, 2019, DCN Number:19063003000001).

Additionally, the ELITONE device has no active medicinal ingredient, so no prescription is needed for FSA. This is not considered medication.

The device is indicated for stress urinary incontinence, which is determined by a “yes” answer to the question: Do you lose urine with physical activity such as coughing, sneezing or running?

The ELITONE device for incontinence fits in both the FSA categories of Physical Therapy and Incontinence Products.

The ELITONE device and GelPads are also registered on the SIGIS database of eligible products:

UPC	Product Desc	FCC	Finest Category	Manufacturer	Status
85109600803	ELIDAH ELITONE REUSABLE GELPADS 5CT	0125	TENS Units & Replacement Pads	ELIDAH	Eligible Item, SIGIS added
85109600805	ELIDAH ELITONE PELVIC FLOOR INCO DEVICE	9427	Mixed/Miscellaneous Reusable Incontinence	ELIDAH	Eligible Item, SIGIS added

If you need more information about the ELITONE device, feel free to call 978-435-4324.

Best regards,

Gloria Kolb

CEO of Elidah, manufacturer of Elitone