



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 and ELITONE URGE devices were FDA-cleared for use at-home, Over-the-Counter (FDA Owner/Operator Number: 10059852, submissions K183585 and K223884). They are pelvic floor muscle stimulator treatments for incontinence, which is a durable medical equipment (approved by CMS).

Additionally, the devices have no active medicinal ingredient, so no prescription is needed for FSA. This is not considered medication.

ELITONE is indicated for stress urinary incontinence, ELITONE URGE is indicated for urge urinary incontinence, and the GelPads are the supplies needed for their use. The ELITONE devices and GelPads fit both the FSA categories of Physical Therapy and Incontinence Products.

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

UPC	Product Desc	FLC	Finest Category	Manufacturer	Status
85109600810	ELIDAH ELITONE URGE INCONTINENCE DEVICE	9427	Mixed/Miscellaneous Reusable Incontinence	ELIDAH	Eligible Item, SIGIS added
85109600803	ELIDAH ELITONE REUSABLE GELPADS SCT	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 products