Medicare Coverage Issues Manual

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
60-24	1 pp.	1 pp.

CORRECTION/CLARIFICATION --*EFFECTIVE DATE: N/A*

Section 60-23, Speech Generating Devices, is corrected to include material that was inadvertently deleted via transmittal 150. The restored text is redlined.

These instructions should be implemented within your current operating budget.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

o May have synthesized speech output, which permits multiple methods of message formulation and multiple methods of device access; or

o May be software that allows a laptop computer, desktop computer or personal digital assistant (PDA) to function as a speech generating device.

Devices that would not meet the definition of speech generating devices and therefore, do not fall within the scope of §1861(n) are characterized by:

o Devices that are not dedicated speech devices, but are devices that are capable of running software for purposes other than for speech generation, e.g., devices that can also run a word processing package, an accounting program, or perform other non-medical function.

o Laptop computers, desktop computers, or PDAs, which may be programmed to perform the same function as a speech generating device, are non-covered since they are not primarily medical in nature and do not meet the definition of DME. For this reason, they cannot be considered speech generating devices for Amedicare coverage purposes.

o A device that is useful to someone without severe speech impairment is not considered a speech generating device for Medicare coverage purposes.

60-24 NON-IMPLANTABLE PELVIC FLOOR ELECTRICAL STIMULATOR

Non-implantable pelvic floor electrical stimulators provide neuromuscular electrical stimulation through the pelvic floor with the intent of strengthening and exercising pelvic floor musculature. Stimulation is generally delivered by vaginal or anal probes connected to an external pulse generator.

The methods of pelvic floor electrical stimulation vary in location, stimulus frequency (Hz), stimulus intensity or amplitude (mA), pulse duration (duty cycle), treatments per day, number of treatment days per week, length of time for each treatment session, overall time period for device use and between clinic and home settings. In general, the stimulus frequency and other parameters are chosen based on the patient's clinical diagnosis.

Pelvic floor electrical stimulation with a non-implantable stimulator is covered for the treatment of stress and/or urge urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training.

A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.

60-25 NONCONTACT NORMOTHERMIC WOUND THERAPY (NNWT)

NNWT is a device reported to promote wound healing by warming a wound to a predetermined temperature. The device consists of a noncontact wound cover into which a flexible, battery powered, infrared heating card is inserted. There is insufficient scientific or clinical evidence to consider this device as reasonable and necessary for the treatment of wounds within the meaning of §1862(a)(1)(A) of the Social Security Act and will not be covered by Medicare.