Medicare Coverage Issues Manual

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

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CHANGE REQUEST 2027

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Table of Contents	2 pp.	2 pp.
60-24 - 60-25	1 pp.	1 pp.

NEW/REVISED MATERIAL --*EFFECTIVE DATE:* July 1, 2002
***IMPLEMENTATION DATE:* July 1, 2002**

Section 60-25, Noncontact Normothermic Wound Therapy (NNWT)

We are adding a new section to the CIM to address our noncoverage decision on the use of normothermic wound therapy. 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 (the Act) and will not be covered by Medicare.

This revision to the Coverage Issues Manual is a national coverage decision (NCD). NCDs are binding on all Medicare carriers, intermediaries, peer review organization, Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also finding on a Medicare+Choice Organization. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(I) of the Act.

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.**

Dialysis Equipment

Durable Medical Equipment

Prosthetic Devices

Braces - Trusses - Artificial Limbs and Eyes

Patient Education Programs

Nursing Services

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

- 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:

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.