Medicare Coverage Issues Manual

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal 132 **Date: NOVEMBER 30, 2000**

CHANGE REQUEST 1328

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Table of Contents	2 pp.	2 pp.
60-9 (Cont.) - 60-9 (Cont.)	4 pp.	4 pp.
60-22 - 60-23 (Cont.)	3 pp.	2 pp.

NEW/REVISED MATERIAL--*EFFECTIVE DATE: January 1, 2001*
IMPLEMENTATION DATE: January 1, 2001

Section 60-9, Durable Medical Equipment Reference List, is revised to reflect a change in the benefit category and coverage status of Augmentative and Alternative Communication Devices. These devices are now considered to fall within the durable medical equipment (DME) benefit category. They will be covered if the contractor's medical staff determines that the patient's medical condition warrants the device based on information found at §60-23 of the Coverage Issues Manual.

Section 60-23, Speech Generating Devices, adds a new section to the DME portion of the Coverage Issues Manual and defines speech generating devices.

Durable Medical Equipment Regional Carriers should publish this information in their next regularly scheduled bulletin.

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

COVERAGE ISSUES

Prosthetic Devices

Braces - Trusses - Artificial Limbs and Eyes

Patient Education Programs

Nursing Services

Durable Medical Equipment Reference List:

Item	Coverage Status
Air Cleaners	--deny--environmental control equipment; not primarily medical in nature (§l86l (n) of the Act)
Air Conditioners	--deny--environmental control equipment; not primarily medical in nature (§l861(n) of the Act)
Air-Fluidized Bed	--(See §60-19.)
Alternating Pressure Pads, and Matresses and Lambs Wool Pads	--covered if patient has, or is highly susceptible to, decubitus ulcers and patient's physician has specified that he will be supervising its use in connection with his course of treatment.
Audible/Visible Signal Pacemaker Monitor	--(See Self-Contained Pacemaker Monitor.)
Augmentative Communication Device	--(See Speech Generating Devices, §60-23.)
Bathtub Lifts	--deny--convenience item; not primarily medical in nature (§l861(n) of the Act)
Bathtub Seats	--deny--comfort or convenience item; hygienic equipment; not primarily medical in nature (§l861(n) of the Act)
Bead Bed-	-(See §60-19.)
Bed Baths (home type)	--deny--hygienic equipment; not primarily medical in nature (§l861(n) of the Act)
Bed Lifter (bed elevator)	--deny--not primarily medical in nature (§1861(n) of the Act.

Bedboards	--deny--not primarily medical in nature (§1861(n) of the Act)
Bed Pans (autoclavable hospital type)	--covered if patient is bed confined
Bed Side Rails	--(See Hospital Beds, §60-l8.)
Beds-Lounge (power or manual)	--deny--not a hospital bed; comfort or convenience item; not primarily medical in nature (§l86l(n) of the Act)
Beds--Oscillating	--deny--institutional equipment; inappropriate for home use
Bidet Toilet Seat	--(See Toilet Seats.)
Blood Glucose Analyzer--Reflectance Colorimeter	--deny--unsuitable for home use (See §60-11.)
Blood Glucose Monitor	--covered if patient meets certain conditions (See §60-11.)
Braille Teaching Texts	--deny--educational equipment; not primarily medical in nature (§1861(n) of the Act)
Canes	--covered if patient's condition impairs ambulation (See §60-3.)
Carafes	--deny--convenience item; not primarily medical in nature (§l861(n) of the Act)
Catheters	--deny--nonreusable disposable supply (§l861(n) of the Act)
Commodes	--covered if patient is confined to bed or room

NOTE: The term "room confined" means that the patient's condition is such that leaving the room is medically contraindicated. The accessibility of bathroom facilities generally

	would not be a factor in this determination. However, confinement of a patient to his home in a case where there are no toilet facilities in the home may be equated to room confinement. Moreover, payment may also be made if a patient's medical condition confines him to a floor of his home and there is no bathroom located on that floor (See hospital beds in §60-18 for definition of "bed confinement".)
Communicator	--(See §60-23, Speech Generating Devices)
Continuous Passive Motion	--Continuous passive motion devices are devices covered for patients who have received a total knee replacement. To qualify for coverage, use of the device must commence within 2 days following surgery. In addition, coverage is limited to that portion of the three week period following surgery during which the device is used in the patient's home. There is insufficient evidence to justify coverage of these devices for longer periods of time or for other applications.
Continuous Positive Airway Pressure (CPAP)	--(See §60-17.)
Crutches	--covered if patient's condition impairs Ambulation
Cushion Lift Power Seat	--(See Seat Lifts.)
Dehumidifiers (room or central heating system type)	--deny--environmental control equipment; not primarily medical in nature (§l861(n) of the Act

Diathermy Machines (standard pulses wave types)	--deny--inappropriate for home use (See and §35-41.)
Digital Electronic Pacemaker Monitor	--(See Self-Contained Pacemaker Monitor.)
Disposable Sheets and Bags	--deny--nonreusable disposable supplies (§l861(n) of the Act)
Elastic Stockings	--deny--nonreusable supply; not rental-type items (§l861(n) of the Act)
Electric Air Cleaners	--deny--(See Air Cleaners.) (§l861(n) of the Act)
Electric Hospital Beds	--(See Hospital Beds §60-18.)
Electrostatic Machines	--deny--(See Air Cleaners and Air Conditioners.) (§l861(n) of the Act)
Elevators	--deny--convenience item; not primarily medical in nature (§l861(n) of the Act)
Emesis Basins	--deny--convenience item; not primarily medical in nature (§l861(n) of the Act)
Esophageal Dilator	--deny--physician instrument; inappropriate for patient use
Exercise Equipment	--deny--not primarily medical in nature (§l861(n) of the Act)
Fabric Supports	--deny--nonreusable supplies; not rental-type it (§l861(n) of the Act)
Face Masks (oxygen)	--covered if oxygen is covered (See § 60-4.)
Face Masks (surgical)	--deny--nonreusable disposable items (§l861(n) of the Act)

- The patient requires treatment with wet soaks or moist wound dressings that are not protected with an impervious covering such as plastic wrap or other occlusive material; an air-fluidized bed;

- The caregiver is unwilling or unable to provide the type of care required by the patient on an air-fluidized bed;

- Structural support is inadequate to support the weight of the air-fluidized bed system (it generally weighs 1600 pounds or more);

- Electrical system is insufficient for the anticipated increase in energy consumption; or

- Other known contraindications exist.

Coverage of an air-fluidized bed is limited to the equipment itself. Payment for this covered item may only be made if the written order from the attending physician is furnished to the supplier prior to the delivery of the equipment. Payment is not included for the caregiver or for architectural adjustments such as electrical or structural improvement.
Cross refer: Carriers Manual, §5102.2.

60-20 TRANSCUTANEOUS ELECTRIC AL NERVE STIMULATORS (TENS)

TENS is a type of electrical nerve stimulator that is employed to treat chronic intractable pain. This stimulator is attached to the surface of the patient's skin over the peripheral nerve to be stimulated. It may be applied in a variety of settings (in the patient's home, a physician's office, or in an outpatient clinic). Payment for TENS may be made under the durable medical equipment benefit. (See §45-25 for an explanation of coverage of medically necessary supplies for the effective use of TENS and §45-19 for an explanation of coverage of TENS for acute post-operative pain.)

60-21 INTRAPULMONARY PERCUSSIVE VENTILATOR (IPV) - NOT COVERED

IPV is a mechanized form of chest physical therapy. Instead of a therapist clapping or slapping the patient’s chest wall, the IPV delivers mini-bursts (more than 200 per minute) of respiratory gasses to the lungs via a mouthpiece. Its intended purpose is to mobilize endobronchial secretions and diffuse patchy atelectasis. The patient controls variables such as inspiratory time, peak pressure and delivery rates.

Studies do not demonstrate any advantage of IPV over that achieved with good pulmonary care in the hospital environment and there are no studies in the home setting. There are no data to support the effectiveness of the device. Therefore, IPV in the home setting is not covered.

60-22 VAGUS NERVE STIMULATION FOR TREATMENT OF SEIZURES

In the past 10 years, there have been significant advances in surgical treatment for epilepsy and in medical treatment of epilepsy with newly developed and approved medications. Despite these advances, 25-50 percent of patients with epilepsy experience breakthrough seizures or suffer from debilitating adverse effects of antiepileptic drugs.

The vagus nerve is a mixed nerve carrying both somatic and visceral afferent and efferent signals. The majority of vagal nerve fibers are visceral afferents with wide distribution. The basic premise of vagus nerve stimulation in the treatment of epilepsy is that vagal visceral afferents have a diffuse central nervous system projection and the activation of these pathways has a widespread effect upon neuronal excitability. Besides activation of well-defined reflexes, vagal stimulation produces evoked potentials recorded from the cerebral cortex, the hippocampus, the thalamus, and the cerebellum.

The vagus nerve stimulation system is comprised of an implantable pulse generator and lead and an external programming system used to change stimulation settings. Clinical evidence has shown that vagus nerve stimulation is safe and effective treatment for patients with medically refractory partial onset seizures, for whom surgery is not recommended or for whom surgery has failed. Vagus nerve stimulation is not covered for patients with other types of seizure disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed.

A partial onset seizure has a focal onset in one area of the brain and may or may not involve a loss of motor control or alteration of consciousness. Partial onset seizures may be simple, complex, or complex partial seizures, secondarily generalized.

60-23 SPEECH GENERATING DEVICES

Effective January 1, 2001, augmentative and alternative communication devices or communicators, which are hereafter referred to as "speech generating devices" are now considered to fall within the DME benefit category established by §1861(n) of the Social Security Act. They may be covered if the contractor's medical staff determines that the patient suffers from a severe speech impairment and that the medical condition warrants the use of a device based on the following definitions.

Definition of Speech Generating Devices

Speech generating devices are defined as speech aids that provide an individual who has a severe speech impairment with the ability to meet his functional speaking needs. Speech generating are characterized by:

- Being a dedicated speech device, used solely by the individual who has a severe speech impairment;
- May have digitized speech output, using pre-recorded messages, less than or equal to 8 minutes recording time;
- May have digitized speech output, using pre-recorded messages, greater than 8 minutes recording time;
- May have synthesized speech output, which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
- 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:

- 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 functions.

- 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 Medicare coverage purposes.

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