Medicare Coverage Issues Manual

Department of Health & Human Services (DHHS)
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HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
60-16 - 60-24	7	8

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

Section 60-17, Continuous Positive Airway Pressure (CPAP), is revised to expand Medicare coverage for CPAP in the use of obstructive sleep apnea (OSA). Medicare contractors must develop a method for monitoring compliance for CPAP devices.

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

Medicare contractors must develop a method for monitoring compliance for CPAP devices.

These instructions should be implemented within your current operating budget.

DISCLAIMER: This 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.

In the case of patients with medical documentation showing severe neurological disorders or restricted use of one hand which makes it impossible for them to use a wheeled walker that does not have a sophisticated braking system, a reasonable charge for the safety roller may be determined without relating it to the reasonable charge for a standard wheeled walker. (Such reasonable charge should be developed in accordance with the instructions in Medicare Carriers Manual §§5010 and 5205.)

Cross Refer: Carriers Manual §§2100ff., §60-9.

60-16. PNEUMATIC COMPRESSION DEVICES

Pneumatic compression devices consist of an inflatable garment for the arm or leg and an electrical pneumatic pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with cycle times and pressures that vary between devices. Pneumatic devices are covered for the treatment of lymphedema or for the treatment of chronic venous insufficiency with venous stasis ulcers.

Lymphedema

Lymphedema is the swelling of subcutaneous tissues due to the accumulation of excessive lymph fluid. The accumulation of lymph fluid results from impairment to the normal clearing function of the lymphatic system and/or from an excessive production of lymph. Lymphedema is divided into two broad classes according to etiology. Primary lymphedema is a relatively uncommon, chronic condition which may be due to such causes as Milroy's Disease or congenital anomalies. Secondary lymphedema, which is much more common, results from the destruction of or damage to formerly functioning lymphatic channels, such as surgical removal of lymph nodes or post radiation fibrosis, among other causes.

Pneumatic compression devices are covered in the home setting for the treatment of lymphedema if the patient has undergone a four-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial. The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression.

Chronic Venous Insufficiency With Venous Stasis Ulcers

Chronic venous insufficiency (CVI) of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers.

Pneumatic compression devices are covered in the home setting for the treatment of CVI of the lower extremities only if the patient has one or more venous stasis ulcer(s) which have failed to heal after a six month trial of conservative therapy directed by the treating physician. The trial of conservative therapy must include a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb.

General Coverage Criteria

Pneumatic compression devices are covered only when prescribed by a physician and when they are used with appropriate physician oversight, i.e., physician evaluation of the patient's condition to determine medical necessity of the device, assuring suitable instruction in the operation of the machine, a treatment plan defining the pressure to be used and the frequency and duration of use, and ongoing monitoring of use and response to treatment.

The determination by the physician of the medical necessity of a pneumatic compression device must include (1) the patient's diagnosis and prognosis; (2) symptoms and objective findings, including measurements which establish the severity of the condition; (3) the reason the device is required, including the treatments which have been tried and failed; and (4) the clinical response to an initial treatment with the device. The clinical response includes the change in pre-treatment measurements, ability to tolerate the treatment session and parameters, and ability of the patient (or caregiver) to apply the device for continued use in the home.

In general, a nonsegmented (HCPCS code E0650) or segmented (HCPCS code E0651) compression device without manual control of pressure in each chamber is considered sufficient to meet the clinical needs of the individual. The only time that a segmented, calibrated gradient pneumatic compression device would be covered is when the individual has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a nonsegmented device.

Cross Refer: §60-9.

60-17. CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP)

CPAP is a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA).

Effective for services furnished between and including January 12, 1987 and March 31, 2002:

The diagnosis of OSA requires documentation of at least 30 episodes of apnea, each lasting a minimum of 10 seconds, during 6-7 hours of recorded sleep. The use of CPAP is covered under Medicare when used in adult patients with moderate or severe OSA for whom surgery is a likely alternative to CPAP.

Initial claims must be supported by medical documentation (separate documentation where electronic billing is used), such as a prescription written by the patient's attending physician, that specifies:

- a diagnosis of moderate or severe obstructive sleep apnea, and
- surgery is a likely alternative.

The claim must also certify that the documentation supporting a diagnosis of OSA (described above) is available.

Effective for services furnished on or after April 1, 2002:

The use of CPAP devices are covered under Medicare when ordered and prescribed by the licensed treating physician to be used in adult patients with OSA if either of the following criteria using the Apnea-Hyopopnea Index (AHI) are met:

AHI ≥ 15 events per hour, or

AHI ≥ 5 and ≤ 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease or history of stroke.

The AHI (Apnea-Hypopnea Index) is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of 2 hours of sleep recorded by polysomnography using actual recorded hours of sleep (i.e, the AHI may not be extrapolated or projected).

Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.

The polysomnography must be performed in a facility - based sleep study laboratory, and not in the home or in a mobile facility.

Initial claims for CPAP devices must be supported by information contained in the medical record indicating that the patient meets Medicare's stated coverage criteria.

Cross Refer: §60-9.

60-18. HOSPITAL BEDS

A. General Requirements for Coverage of Hospital Beds.--A physician's prescription, and such additional documentation as the contractors' medical staffs may consider necessary, including medical records and physicians' reports, must establish the medical necessity for a hospital bed due to one of the following reasons:

o The patient's condition requires positioning of the body; e.g., to alleviate pain, promote good body alignment, prevent contractures, avoid respiratory infections, in ways not feasible in an ordinary bed; or

o The patient's condition requires special attachments that cannot be fixed and used on an ordinary bed.

B. Physician's Prescription.--The physician's prescription, which must accompany the initial claim, and supplementing documentation when required, must establish that a hospital bed is medically necessary. If the stated reason for the need for a hospital bed is the patient's condition requires positioning, the prescription or other documentation must describe the medical condition, e.g., cardiac disease, chronic obstructive pulmonary disease, quadriplegia or paraplegia, and also the severity and frequency of the symptoms of the condition, that necessitates a hospital bed for positioning.

If the stated reason for requiring a hospital bed is the patient's condition requires special attachments, the prescription must describe the patient's condition and specify the attachments that require a hospital bed.

C. Variable Height Feature.--In well documented cases, the contractors' medical staffs may determine that a variable height feature of a hospital bed, approved for coverage under subsection A above, is medically necessary and, therefore, covered, for one of the following conditions:

o Severe arthritis and other injuries to lower extremities; e.g., fractured hip. The condition requires the variable height feature to assist the patient to ambulate by enabling the patient to place his or her feet on the floor while sitting on the edge of the bed;

o Severe cardiac conditions. For those cardiac patients who are able to leave bed, but who must avoid the strain of "jumping" up or down;

o Spinal cord injuries, including quadriplegic and paraplegic patients, multiple limb amputee and stroke patients. For those patients who are able to transfer from bed to a wheelchair, with or without help; or

o Other severely debilitating diseases and conditions, if the variable height feature is required to assist the patient to ambulate.

D. Electric Powered Hospital Bed Adjustments.--Electric powered adjustments to lower and raise head and foot may be covered when the contractor's medical staff determines that the patient's condition requires frequent change in body position and/or there may be an immediate need for a change in body position (i.e., no delay can be tolerated) and the patient can operate the controls and cause the adjustments. Exceptions may be made to this last requirement in cases of spinal cord injury and brain damaged patients.

E. Side Rails.--If the patient's condition requires bed side rails, they can be covered when an integral part of, or an accessory to, a hospital bed.

Cross refer: Carriers Manual, §5015.4

60-19. AIR-FLUIDIZED BED (Effective for services rendered on or after: 07/30/90)

An air-fluidized bed uses warm air under pressure to set small ceramic beads in motion which simulate the movement of fluid. When the patient is placed in the bed, his body weight is evenly distributed over a large surface area which creates a sensation of "floating." Medicare payment for home use of the air-fluidized bed for treatment of pressure sores can be made if such use is reasonable and necessary for the individual patient.

A decision that use of an air-fluidized bed is reasonable and necessary requires that:

o The patient has a stage 3 (full thickness tissue loss) or stage 4 (deep tissue destruction) pressure sore;

o The patient is bedridden or chair bound as a result of severely limited mobility;

o In the absence of an air-fluidized bed, the patient would require institutionalization;

o The air-fluidized bed is ordered in writing by the patient's attending physician based upon a comprehensive assessment and evaluation of the patient after completion of a course of conservative treatment designed to optimize conditions that promote wound healing. This course of treatment must have been at least one month in duration without progression toward wound healing. This month of prerequisite conservative treatment may include some period in an institution as long as there is documentation available to verify that the necessary conservative treatment has been rendered.

o Use of wet-to-dry dressings for wound debridement, begun during the period of conservative treatment and which continue beyond 30 days, will not preclude coverage of air-fluidized bed. Should additional debridement again become necessary, while a patient is using an air-fluidized bed (after the first 30-day course of conservative treatment) that will not cause the air-fluidized bed to become non-covered. In all instances documentation verifying the continued need for the bed must be available.

o Conservative treatment must include:

- Frequent repositioning of the patient with particular attention to relief of pressure over bony prominences (usually every 2 hours);

- Use of a specialized support surface (Group II) designed to reduce pressure and shear forces on healing ulcers and to prevent new ulcer formation;

- Necessary treatment to resolve any wound infection;

- Optimization of nutrition status to promote wound healing;

- Debridement by any means (including wet to dry dressings-which does not require an occlusive covering) to remove devitalized tissue from the wound bed;

- Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings protected by an occlusive covering, while the wound heals.

o A trained adult caregiver is available to assist the patient with activities of daily living, fluid balance, dry skin care, repositioning, recognition and management of altered mental status, dietary needs, prescribed treatments, and management and support of the air-fluidized bed system and its problems such as leakage;

o A physician directs the home treatment regimen, and reevaluates and recertifies the need for the air-fluidized bed on a monthly basis; and

o All other alternative equipment has been considered and ruled out.

Home use of the air-fluidized bed is <u>not covered</u> under any of the following circumstances:

o The patient has coexisting pulmonary disease (the lack of firm back support makes coughing ineffective and dry air inhalation thickens pulmonary secretions);

o 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;

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

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

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

o 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 ELECTRICAL 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;

- 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:

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.