

Medicare Coverage Issues Manual

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<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
Table of Contents	2 pp.	2 pp.
60-16 – 60-19 (Cont.)	4 pp.	4 pp.

NEW/REVISED MATERIAL--EFFECTIVE DATE: January 14, 2002
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Section 60-16, Pneumatic Compression Devices, clarifies the policy by dividing the policy into 2 separate parts based on indications and establishes different coverage criteria for the 2 different indications.

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

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 binding on a 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.)

These instructions should be implemented within your current operating budget.

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

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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) (Effective for Claims Adjudicated on and After January 12, 1987.)

CPAP is a non-invasive technique for providing low 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). 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:

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

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

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 not covered 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);