Medicare Coverage Issues Manual

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

Transmittal 151 Date: JANUARY 14, 2002

CHANGE REQUEST 1944

HEADER SECTION NUMBERS PAGES TO INSERT PAGES TO DELETE

60-16 – 60-19 (Cont.) 2 pp. 2 pp.

NEW/REVISED MATERIAL--EFFECTIVE DATE: January 14, 2002 IMPLEMENTATION DATE: January 14, 2002

<u>Section 60-16, Pneumatic Compression Devices</u>, is revised to clarify the language previously found in CR 1944, Transmittal Number 148, dated December 11, 2001, so that it is clear when segmented, calibrated gradient pneumatic compression devices will be covered.

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 Section 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.

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 6 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.

The only time that a segmented, calibrated gradient pneumatic compression device (HCPCs code E0652) would be covered is when the individual has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a nonsegmented device in conjunction with a segmented appliance or a segmented compression device without manual control of pressure in each chamber.

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:

- 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.

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