HCFA Rulings

Department of Health and Human Services

Health Care Financing Administration

Ruling No. 96-1

Date: September 1996

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

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This Ruling states the policy of the Health Care Financing Administration regarding the distinction between the statutory benefits of "orthotics" and "durable medical equipment" under Medicare Part B. The distinction may have an effect on the Medicare approved amount of payment and is necessary in those instances where items are furnished in

skilled nursing facilities that meet the definition in section 1819(a)(1) of the Social Security Act (the Act) or hospitals due to the express exclusion from Part B coverage of durable medical equipment when used in a hospital or skilled nursing facility.

The Ruling clarifies that the "orthotics" benefit in section 1861(s)(9) of the Act, insofar as braces are concerned, is limited to leg, arm, back, and neck braces that are used independently rather than in conjunction with, or as components of, other medical or non-medical equipment. It also clarifies that accessories used in conjunction with, and necessary for the full functioning of, durable medical equipment fall under the durable medical equipment benefits category. Finally, the Ruling provides several examples that illustrate the application and scope of these two terms.

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MEDICARE PROGRAM

Medicare Supplementary Medical Insurance (Part B)

CLARIFICATION OF THE TERMS "ORTHOTICS," "BRACES," AND "DURABLE MEDICAL EQUIPMENT" UNDER MEDICARE PART B

HELD: The "orthotics" benefit described in section 1861(s)(9) of the Social Security Act, insofar as braces are concerned, is limited to leg, arm, back, and neck braces that are used independently, rather than in conjunction with, or as components of, other medical or non-medical equipment. It is also held that leg, arm, back, and neck braces used in conjunction with, and necessary for the full functioning of, durable medical equipment are accessories to the durable medical equipment and, hence, subject to the requirements of section 1861(n) of the Social Security Act.

CITATIONS: Sections 1834(a)(4) and (h) and 1861(n) and (s)(9) of the Social Security Act (42 U.S.C. 1395m(a)(4) and (h) and 1395x(n) and (s)(9); and 42 CFR 414.202.

BACKGROUND

The Medicare program's long-standing policy has been to limit payment for "orthotics" under Medicare Part B to leg,

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arm, back, and neck braces that are stand-alone devices used independently of other kinds of medical equipment. Recent decisions issued by administrative law judges and Medicare carrier hearing officers have, however, diverged from this policy and have interpreted section 1861(s)(9) of the Act, insofar as braces are concerned, as encompassing all devices that serve to support or restrict motion in a part of the body, even if the devices may not reasonably be used on their own and are primarily intended to be used with other equipment. The purpose of this Ruling is to provide clarification and guidance regarding the scope and meaning of the statutory benefits for "orthotics" and "durable medical equipment."

ORTHOTICS

Section 1834(h) of the Social Security Act (the Act) provides for payment of "orthotics and prosthetics" as described "in section 1861(s)(9)[.]" Section 1861(s)(9) of the Act in turn lists only the following:

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition[.]

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In light of this limited statutory language, we defined "orthotic devices" in 42 CFR 414.202 of our regulations, which states in pertinent part:

Prosthetic and orthotic devices means--

(3) Leg, arm, back, and neck braces, and artificial
legs, arms, and eyes, including replacements if required because of a change in the beneficiary's physical condition. (Emphasis added).

DURABLE MEDICAL EQUIPMENT

In contrast to the very specific wording of section 1861(s)(9) of the Act, section 1861(n) of the Act employs an open-ended reference to what constitutes "durable medical equipment" by stating that the term "includes" items, such as oxygen tents, hospital beds, and wheelchairs, that may be used in the home. Our definition of durable medical equipment set forth at 42 CFR 414.202, in part, tracks this language by referring in a similarly open-ended manner to medical equipment that can withstand repeated use and is appropriate for use in the home. In light of the breadth of the durable medical equipment category set forth in the statute and regulation, section 2100.5 of the Medicare Carrier's Manual, Part 3 - Claims Process, "Coverage of Supplies and Accessories," provides that

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payment for durable medical equipment extends to coverage of "supplies and accessories" that are "necessary for the effective use of durable medical equipment."

SEATING DEVICES AS AN EXAMPLE OF DURABLE MEDICAL EQUIPMENT

Many items, including wheelchairs and hospital beds (both expressly classified as durable medical equipment under section 1861(n) of the Act and section 2100.1 of the Medicare Carrier's Manual, Part 3 - Claims Process, "Definition of Durable Medical Equipment"), support portions of the body. Other items, such as splints or casts (both classified under section

1861(s)(5) of the Act), protect or restrict movement of a portion of the body. None of these items is appropriately classified as a "brace" under section 1861(s)(9) of the Act. (We also generally exclude orthopedic shoes or other shoe inserts or supportive devices for the feet from coverage.)

To the extent that a wheelchair seating system or other equipment may or may not function properly or not achieve its full "therapeutic benefit" without attached components supporting or restricting motion in a body part, the attachments are appropriately viewed as a necessary accessory that is an integral part of the durable medical equipment and is, accordingly, payable as durable medical equipment, provided that the other prerequisites for classification as durable medical equipment are met.

Many seating systems (including wheelchairs) incorporate as integral parts various rests and supporting and positional attachments that are modifications of the seating system and that are intended to be used with the seating system to which they are attached. Section 1861(n) of the Act expressly classifies wheelchairs as durable medical equipment. Furthermore, the legislative history and prior Congressional enactments evidence no intent to classify separately integral components or attachments to seating systems as "braces."

Section 4152(c)(4) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990), Public Law 101-508, enacted on November 5, 1990, amended section 1834(a)(4) of the Act, governing customized durable medical equipment, to extend coverage to customized wheelchairs that have been "measured, fitted, or adapted in consideration" of a patient's "disability" and including "customized features, modifications, or components" in "accordance with instructions from the patient's physician." The Congress explained that these customized features could "include, but are not limited to" items such as "attachments to convert wheelchairs to one-armed drive," "postural control devices," and "custom molded cushions and inserts or lateral

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supports." (House Report No. 101-881, 101st Cong., 2d Sess., 1990 USCCAN at 2270.) Thus, ample evidence establishes that the Congress intended sophisticated wheelchairs, including chairs with functional attachments, to be classified in their totality as durable medical equipment.

Even though the Congress was addressing customized wheelchairs, the intent to classify this equipment in its totality as durable medical equipment extends by analogy to ordinary wheelchairs with attachments. Taken together with the narrow wording of section 1861(s)(9) of the Act, the Congress's treatment of attachments to wheelchairs thus strongly supports the conclusion that a device supporting or restricting motion in a body part but that is an integral part of other equipment is not appropriately classified under the brace benefits category set forth in section 1861(s)(9) of the Act. Our long-standing policy governing the breadth of the durable medical equipment benefits category reflects this congressional intent.

CONCLUSION AND ILLUSTRATIONS

For the reasons set forth above, we therefore conclude that "orthotics" payable under section 1861(s)(9), insofar as braces are concerned, and sections 1834(a) and (h) of the Act are properly limited to leg, arm, back, and neck braces

that are stand-alone devices used independently of other kinds of medical equipment. When a device that supports or restricts motion in a part of the body is not generally used, or may not reasonably be used, on its own and is primarily intended to be used with other medical or non-medical equipment payable as durable medical equipment, the durable medical equipment benefits category, and not the brace benefits category, applies.

Following are three examples that illustrate the application and scope of the terms "orthotics" and "durable medical equipment":

Illustration 1. A supplier manufactures and supplies medical devices to individuals who are generally elderly and suffer from Alzheimer's or other debilitating neuromuscular diseases that have caused them to be nonambulatory, immobile, and confined to a chair or bed. Due to their immobility, these patients may suffer from secondary complications, such as pressure sores, multisited contractures, musculoskeletal degeneration and deformities, and circulatory problems.

Under a physician's order, the supplier furnishes individually fitted attachments designed to be used in conjunction with a chair to seat and position the patient. The attachments, which the supplier labels "orthotic braces," are alleged to position limbs and other body parts

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properly; restrict motion or weight bearing; immobilize and protect weak musculoskeletal segments; reduce load; retard progression of musculoskeletal deformity; and improve function. The design of the supplier's "orthotic braces" requires them to be attached to the chair frame, and the "orthotic braces" cannot function or be used apart from the chair to which they are attached.

Discussion: Although the devices in question may support or restrict movement in parts of the body, they are not braces within the meaning of 1861(s)(9) of the Act because they are integral parts of a seating system and are not designed or intended to be used apart from the seating system.

Illustration 2. A supplier furnishes what it describes as a lumbar support cushion comprised of a number of attachment straps and front and back cushions molded to fit the patient's body. The device is alleged to supply corrective support and pressure to the back to address postural defects and conditions such as scoliosis (curvature of the spine). Although capable of being worn separately while standing or lying down, the device is designed to fit into a seated base. In practice, the device is also predominantly worn and used while the patient is seated and is most frequently used by patients who are largely chairbound.

Discussion: Although the device in question may support or restrict movement in parts of the body, it is primarily intended to be used in conjunction with a seat and is comparable to a custom molded cushion or seat insert. The support cushion is accordingly not a brace within the meaning of section 1861(s)(9) of the Act.

Illustration 3. A supplier manufactures a sophisticated hospital bed with motorized sections that may be individually adjusted to position the patient's body and with straps and lateral support devices that provide support and limit movement of the patient's extremities, including limbs. The bed, with its lateral supports, is used with patients who have suffered severe accident trauma, including potential spinal cord injury, and who must be carefully positioned with limited motion to prevent further injury.

Discussion: Although the lateral supports, straps, and motorized sections support and restrict motion in parts of the body, all of these features are integral parts of a hospital bed, which is classified as durable medical equipment, and these components may therefore not be separately categorized as braces under section 1861(s)(9) of the Act.

HELD: The "orthotics" benefit described in section 1861(s)(9), insofar as braces are concerned, and

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sections 1834(a) and (h) of the Social Security Act is limited to leg, arm, back, and neck braces that are used independently, rather than in conjunction with, or as components of, other medical or non-medical equipment. It is also held that leg, arm, back, and neck braces used in conjunction with, and necessary for the full functioning of, durable medical equipment are accessories to the durable medical equipment and, hence, subject to the requirements of section 1861(n) of the Social Security Act.

EFFECTIVE DATE

This Ruling is effective September 18 , 1996.

Dated: 9/18/96

Bruce C. Vladeck, Administrator, Health Care Financing Administration



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