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DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Social Security Administration
OFFICE OF HEARINGS AND APPEALS

DECISION

IN THE CASE OF	CLAIM FOR
Marguerite C. B[redacted] (Appellant)	Supplemental Medical Insurance Medicare-Part B
William M. B[redacted] (Deceased) (Beneficiary)	094-16-7692 A (HICN/SSN)
United HealthCare Region A DMERC (Intermediary/Carrier/HMO)	999-07-4119 (Docket Number)

This case is before the undersigned Administrative Law Judge on a request for hearing filed on behalf of the deceased beneficiary by his widow, Marguerite C. B[redacted].

A hearing was held before the Administrative Law Judge on June 13, 2001, at the Office of Hearings and Appeals, 300 Pearl Street, Buffalo, New York. The beneficiary's daughter, Barbara B[redacted], appeared and testified. Their representative is William J. Cotter, Esq.

ISSUES

The general issue is whether payment may be made, under the Medicare-Part B program of Title XVIII of the Social Security Act, for an augmentative communication device (CPT code A9270) rented by the beneficiary on January 20, 1998, and purchased by the beneficiary (with accessories) on February 26, 1998. The specific issues are whether the augmentative communication device is precluded from coverage under the Medicare program, or whether the item (and related accessories) at issue is covered under sections 1861(n) and (s)(6) of the Act and Health Care Financing Administration (HCFA) regulations 42 CFR sections 410.38 and 414.202.

APPLICABLE LAW AND REGULATIONS

The Medicare program of Title XVIII of the Social Security Act ("Act") is administered by the Centers for Medicare and Medicaid Services ("CMS"), formally known as the Health Care Financing Administration ("HCFA"). The old and new names of the Medicare agency may be used interchangeably in this decision.

Section 1832 of the Act establishes the scope of the benefits provided under the Medicare Part B supplementary medical insurance (SMI) program. Section 1861 of the Act and Health Care Financing Administration regulation 42 CFR 410.3 defines many of the kinds of medical and other health services which are covered under Medicare, subject to various conditions, limitations, and exclusions.

Section 1862(a) of the Act states, in pertinent part:

> "Notwithstanding any other provision of this title, no payment may be made under Part A or Part B for any expenses incurred for items or services--
>
> (1)(A) which ... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member...;
>
> (6) which constitute personal comfort items (except in the case of Hospice care, as is otherwise permitted under paragraph (1)(C)."

(See also HCFA regulation 42 CFR 411.15(j) and (k))

Section 1832 of the Act states, in pertinent part:

> "(a) The benefits provided to an individual by the insurance program established by this part shall consist of--
>
> (1) entitlement to have payment made to him or on his behalf (subject to the provisions of this part) for medical or other health services."

Section 1861(s)(6) of the Act provides that the term "medical and other health services" includes "durable medical equipment."

Section 1861(n) of the Act provides that the term "durable medical equipment" includes such items as iron lungs, oxygen tents, hospital beds, and wheelchairs that are used in the patient's home, whether furnished on a rental basis or purchased.

HCFA Regulation 42 CFR 410.38 provides, in pertinent part:

> "(a) Medicare Part B pays for the rental or purchase of durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.
>
> (b) An institution that is used as a home may not be a hospital or a SNF as defined in sections 1861(e)(1) and 1861(j)(1) of the Act, respectively.

* * *

(g) As a requirement for payment, HCFA may determine through carrier instructions, or carriers may determine that an item of durable medical equipment requires a written physician order before delivery of the item."

HCFA regulation 42 CFR 414.202 provides, in pertinent part:

"Durable Medical Equipment means equipment, furnished by a supplier or a home health agency that--

(1) Can withstand repeated use;

(2) Is primarily and customarily used to serve a medical purpose;

(3) Generally is not useful to an individual in the absence of an illness or injury; and

(4) Is appropriate for use in the home."

Section 2100 of the Medicare Carriers Manual further provides that expenses for the rental or purchase of durable medical equipment are reimbursable if three requirements are met. These requirements are: (1) the equipment meets the definition of durable medical equipment; (2) the equipment is necessary and reasonable for the treatment of the beneficiary's illness or injury or to improve the functioning of a malformed body member; and (3) the equipment is used in the beneficiary's home.

HCFA regulation 42 CFR 405.860 explains that HCFA makes National Coverage Determinations ("NCDs") granting, limiting or excluding Medicare coverage for specific medical services, procedures or devices (as provided for in section 1869(b)(3) and 1872(a)(2) of the Act). All NCDs are published in the Federal Register and listed in the "Coverage Issues Manual." NCDs are based either on section 1862(a) of the Act or on other applicable sections of the Act. The Forward to the Coverage Issues Manual explains that all NCDs that deny coverage are based on the "not reasonable and necessary" exclusion of section 1862(a)(1) of the Act, unless it is specifically stated in the NCD that the denial is based on another section of the Act. And, where another section of the Act is specifically mentioned as the basis for an NCD, that is the sole authority for the NCD.

Section 60-9 of the Coverage Issues Manual is a national coverage determination (NCD) comprised of the durable medical equipment reference list. That list is designed as a quick reference tool for determining the coverage status of certain items for equipment.

As pertinent in this case for the communication device purchased for the beneficiary in 1998, section 60-9 specifies the following as the NCD with respect to a light writer:

> "communicator: deny – convenience item; not primarily medical in nature (§1861(n) of the Act)."

Section 60-23 of the Coverage Issues Manual provides that, 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. 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.

HCFA regulation 405.860(a) provides that a published NCD is binding on all Medicare carriers in adjudicating initial claims and carrier appeals. Section 1869(b)(3) of the Act and 42 CFR 405.860(b) provide that NCDs that are based on section 1862(a)(1) also are binding on Administrative Law Judges in hearing level adjudications. An Administrative Law Judge may not review NCDs made under section 1862(a)(1) with respect to whether a particular type or class of items or services is covered under the Medicare statute. HCFA's determinations in the Medicare Coverage Issues Manual concerning the reasonableness and necessity of services under section 1862(a)(1) are not reviewable by an Administrative Law Judge, except to the extent that the specific requirements in the national coverage determination have or have not been met in the particular case.

An Administrative Law Judge is not bound by, and may review, NCDs that are based on sections of the Act other than section 1862(a)(1). Where an NCD is not based on section 1862(a)(1) of the Act, an Administrative Law Judge may recognize the NCD as an HCFA policy statement and may afford it any appropriate deference. However, the Administrative Law Judge must fully consider the coverage issue within the context of the specified statutory basis for the NCD and all applicable Medicare coverage standards.

DISCUSSION

The Medicare Part B claim at issue in this case was submitted by the supplier to United HealthCare, the DME Regional Contractor (the "Carrier") at the request of the beneficiary's family. The supplier did not accept assignment with respect to the claim. The claim was for a one-month rental (January 20, 1998) and purchase (February 26, 1998) of an augmentative communication device (Lightwriter SC35, with external speaker, carrying case and shipping). After an initial determination, a review by the Carrier, and a hearing by a Carrier hearing officer, it was determined that no reimbursement could be made for the items in question. More specifically, it was determined that Medicare coverage for a communication device was precluded under Coverage Issues Manual section 60-9 and the "communicator" national coverage determination (NCD), which categorized the device as a convenience item not primarily medical in nature (Exhibits 2 and 5). The beneficiary died in July 1998. His wife, Marguerite C. Bukowski, filed the request for an Administrative Law Judge hearing to appeal the denial of coverage.

The actual cost of the items was as follows: $100.00 for initial one-month rental; $3,970.00 for purchase of Lightwriter; $50.00 for external speaker; $40.00 for case; $20 for shipping. Although the fair hearing decision indicates that the total cost was $4180.00, that did not take into consideration that the $100.00 rental charge was credited toward the purchase price, leaving

a net cost of $4080.00. Therefore, after deduction for the 20% Medicare co-payment, the net "amount in controversy" is $3264.00 (not $3344.00 stated in the fair hearing decision).

The beneficiary was diagnosed with amyotrophic lateral sclerosis ("ALS") in September 1996. As the disease progressed, his ability to orally communicate gradually deteriorated. The beneficiary's daughter testified that his ability to write legibly also deteriorated as the disease progressed and that he became increasingly incapable of communicating his symptoms and needs to his physicians, caregivers and family. In a note dated November 25, 1997, Daniel A. Castellani, M.D., the treating neurologist, cited the related diagnosis of bulbar palsy and referred the beneficiary for speech/language evaluation of his suitability for use of a communication device (Exhibit 10). That evaluation confirmed that the beneficiary's ALS and resulting dysarthria severely limited his verbal expression and precluded intelligible speech (Exhibits 11, 12 and 15). However, the beneficiary's cognitive function and linguistic abilities were intact. He retained sufficient eye-hand coordination and inherent language skills to effectively utilize a speech augmentation device. The speech/language specialists recommended the Lightwriter SL35 with external speaker for use by the beneficiary. Because he remained ambulatory, a carrying case also was recommended for portability.

In a subsequent report dated April 20, 1999, Dr. Castellani noted that, by the time the communication device was ordered, the beneficiary's ALS and bulbar palsy had progressed to the point where he could not swallow or speak (Exhibit 14). Another treating physician, pulmonologist Norman J. Sfeir, M.D., similarly reported that the beneficiary's ALS resulted in respiratory difficulty and complete paralysis of the muscles of phonation and deglutition (Exhibit 16). Dr. Castellani and Dr. Sfeir each opined that the beneficiary required the Lightwriter to communicate with his physicians, caregivers and family.

In the Carrier hearing decision, the Hearing Officer acknowledged that the communication device provided significant therapeutic benefits to the beneficiary (Exhibit 5, p.3). However, the Hearing Officer correctly noted that, at that level of Medicare adjudication and appeal, she was bound by the provisions of Coverage Issues Manual section 60-9 and the National Coverage Determination (NCD) contained therein, which precluded coverage for such communication devices. Accordingly, the Hearing Officer had no option but to deny Medicare coverage for the device.

However, as explained above, the restrictions applicable to determinations made at the Carrier level do not necessarily apply at the Administrative Law Judge hearing level. In this instance, the NCD regarding communication devices is specifically based on section 1861(n) of the Act (the definition of durable medical equipment) and not on section 1862(a)(1) (reasonable and necessary). Therefore, the Administrative Law Judge may (and, indeed, has the obligation to) review the HCFA policy position regarding coverage for communication devices to determine whether, in this particular case, the device may be considered "durable medical equipment" and medically "reasonable and necessary."

There is no question that the Lightwriter device is an item that can withstand repeated use and which is appropriate for use in the patient's home. As to the medical nature of such device, it

would have no practical use in the absence of illness or injury that deprived the patient of the ability to communicate orally. Accordingly, it is primarily and customarily used to serve a medical purpose. The fact that even the HCFA has more recently modified its formal position with respect to coverage for communication devices in NCD 60-23 demonstrates that, as a practical matter, such devices may properly be considered as durable medical equipment. While that policy modification could not be applied at the Carrier level for items supplied prior to January 1, 2001, the Act and Regulations do not preclude the Administrative Law Judge from applying similar logic retroactively in appropriate cases (section 1869(b)(3) of the Act; 42 CFR 405.806). Accordingly, in this case, it is found that the Lightwriter supplied to the beneficiary met the definition of durable medical equipment in section 1861(n) of the Act.

The second requirement before Medicare coverage can be approved is that the Lightwriter must have been medically "reasonable and necessary" for the beneficiary. In this case, the device proved essential in allowing a severely impaired ALS victim to communicate his symptoms, needs and concerns to his physicians, caregivers and family during the final seven months of his life. This is precisely the type of situation that the more recent policy statement of NCD 60-23 was intended to recognize as consistent with medical necessity under the Medicare program. The testimony of the beneficiary's daughter and the statements of the treating physicians in this particular case establish that the device and accessories in question were medically reasonable and necessary for treatment of the beneficiary's disease, and I so conclude.

Accordingly, Medicare payment may be approved for the rental and purchase of the Lightwriter (SL35) and specified accessories.

FINDINGS

After careful consideration of the entire record, the undersigned Administrative Law Judge makes the following findings:

1. The amount in controversy is $3,264.00.

2. The following equipment was provided to William M. B[redacted] by Upstate Communication Resource on January 20, 1998 (one month rental) and February 26, 1998 (purchase): Lightwriter SC35, external speaker, carrying case, and shipping (with $100.00 rental credit).

3. The described equipment does meet the definition of durable medical equipment (§1861(n) of the Act; 42 CFR §414.202).

4. The equipment was made to withstand repeated use, was primarily and customarily used to serve a medical purpose, was used in the beneficiary's home, and was generally not useful absent a relevant medical condition (§1861(n) of the Act; 42 CFR §414.202).

5. The equipment was reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member (§1862(a)(1)(A) of the Act; 42 CFR §411.15(k)).

6. The equipment at issue is covered under the provisions of section 1861(n) of the Act and HCFA regulations 42 CFR section 414.202.

DECISION

It is the decision of the undersigned that the following services, supplies and/or equipment at issue are covered under the provisions of section 1861(n) and 1862(a)(1) of the Social Security Act. Therefore, the Carrier is directed to determine the allowable amount for the specified items and to make appropriate payment under Part B of Title XVIII of the Social Security Act.

Eric L. Glazer
U.S. Administrative Law Judge

September 27, 2001
Date