

MRS. GORE'S OFFICE

PHOTOCOPY
PRESERVATION

MELISSA PRESTON

Sarah -

Marsha Scott's office
needs a response to this
letter concerning the MH
Conference.

Thanks Sarah, and
let me know if I can
be of assistance.

MP

No Administrative
Decision →

Position Being
discussed next week -
Lisa will keep you
updated.

PHOTOCOPY
PRESERVATION

Office of the Chairwoman

U.S. Equal Employment Opportunity Commission
Office of the Chairwoman
1801 L Street, N.W.
Washington, D.C. 20507
(202) 663-4001
FAX: (202) 663-4110

*Step -
How is this being
answered? By whom?*

FAX TRANSMITTAL

DATE: 7/15/99 TIME: 4:13 pm
TO: Ms. Marsha Scott
ORGANIZATION: Office of Presidential Personnel
FAX NUMBER: (202) 456-2259
SENDER: Michelle Waldron
SENDER'S TELEPHONE #: (202) 663-4001
DOCUMENT: Letter to Mrs. Gore
of Pages Transmitted (including cover): 3
SPECIAL INSTRUCTIONS:

PLEASE TELEPHONE SENDER IF YOU DO NOT RECEIVE ALL DOCUMENTS.



U.S. EQUAL EMPLOYMENT OPPORTUNITY COMMISSION
Washington, DC 20507

Office of
the Chairwoman

July 9, 1999

Mrs. Mary Elizabeth Gore
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20501

Dear Mrs. Gore:

A few weeks ago, you chaired the first-ever White House Conference on Mental Health, successfully focusing public attention on the need to end stigma and discrimination against individuals with mental illnesses. Conference participants heard about the reluctance of many people to seek treatment, despite recent and well-publicized medical advances, simply because of the stigma that they might experience as a consequence.

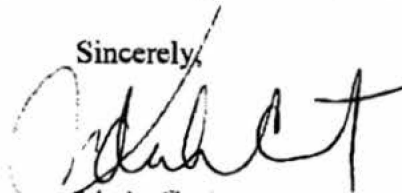
I write to you today to express my deep concern about the recent Supreme Court decision in *Sutton v. United Air Lines*, ___ U.S. ___, No. 97-1943 (June 22, 1999), which may have the unfortunate effect of reinforcing this reluctance to seek treatment for mental illnesses. In *Sutton* and its two companion cases,¹ the Supreme Court announced that "individuals who take medicine to lessen the symptoms of an impairment" can only be considered "individuals with disabilities" for purposes of the Americans with Disabilities Act (ADA) if they "nevertheless remain substantially limited" even after considering all of the positive (and negative) effects of their medication. *Sutton*, ___ U.S. ___, No. 97-1943, slip op. at 15. As a result of this decision, the employment discrimination protections of the ADA may no longer extend to individuals who use medication to treat conditions such as depression or bipolar disorder with a reasonable degree of success. These individuals, however, remain highly vulnerable to employment discrimination and other consequences of stigma when current or prospective employers learn that they have mental illnesses. This stigma, coupled with the loss of ADA employment discrimination protection, may combine to reinforce the reluctance of many people to seek treatment for mental illnesses.

¹ *Murphy v. United Parcel Service, Inc.*, ___ U.S. ___, No. 97-1992 (June 22, 1999); *Albertsons, Inc. v. Kirkingburg*, ___ U.S. ___, No. 98-591 (June 22, 1999).

Letter to Mrs. Gore
July 9, 1999
Page 2

I am profoundly concerned that *Sutton* has the potential to turn the clock back on a decade of progress for individuals with mental illnesses. As the Administration develops a response to these Supreme Court cases, I look forward to being of assistance to you.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ida L. Castro', written over the word 'Sincerely,'.

Ida L. Castro
Chairwoman

cc: Marsha Scott
Deputy Assistant to the President
Deputy Director of Presidential Personnel

Jonathan Young
Associate Director, Office of Public Liaison

NUSGART CONSULTING, LLC
5225 POOKS HILL ROAD SUITE 1626 NORTH
BETHESDA, MARYLAND 20814

TELEPHONE: (301) 530-7846

FAX: (301) 530-7946

E-MAIL: nusgart@erols.com

July 20, 1999

Mrs. Tipper Gore
Office Of The Vice President
Room 200
Old Executive Office Building
Washington, DC 20501

Attention: Audrey Haynes

Re: **Medicare Coverage Of AAC Devices/Dynavox**

Dear Mrs. Gore:

I enjoyed our conversation at the Women For Gore luncheon at Debbie Seibert's in Annapolis several weeks ago, including the discussion with Susan Brown, the impressive woman who has ALS (Lou Gehrig's disease). We spoke about augmentative communication devices ("AAC Devices"), including the Dynavox, which give a person with severe expressive communication disabilities (inability to speak, use sign language, or write because of cerebral palsy, stroke, ALS, or muscular dystrophy etc.) the invaluable ability to speak/communicate. In turn, these people lead more productive, safer and enjoyable lives. Susan Brown is such a person, and she now needs an AAC Device.

These AAC Devices are funded by every contiguous State's Medicaid program, hundreds of commercial health insurance providers, and at the Federal level by the VA, TRICARE (formerly CHAMPUS). Despite this, Medicare does not cover ACC Devices.

Over a decade ago, HCFA issued a National Coverage Determination that AAC Devices would not be covered by Medicare since they were classified as "communicators" and were deemed to be a convenience that was not primarily medical in nature. Since this determination (HCFA has no relevant records on this determination and cannot even say which device they evaluated) there have been significant new technology developments and changes in AAC Devices (e.g. the Dynavox was not introduced until 1991). Moreover, as indicated, Medicaid, health insurance providers, VA, TRICARE do provide coverage. So HCFA's position on Medicare coverage is now outdated and inappropriate.

All of the leading disability organizations support Medicare coverage for AAC Devices, including the ALS Association. HCFA's current position of no Medicare coverage hurts individuals who need AAC Devices.

When we spoke about this at the Sieberts, you had commented that in so many cases the basis for HCFA's coverage policies are predicated on fraud and abuse concerns. However, in this particular situation we agreed that this thought process certainly does not apply since patients who have these diseases definitely need this valuable devices to communicate and lead productive lives. You very graciously indicated you would like to help to ensure that these devices obtain coverage under the Medicare program, and we would be pleased to meet with you or your designee on this very important issue.

Thank you so much for your leadership and concern.

Sincerely,

A handwritten signature in cursive script, reading "Marcia Nussgart R.Ph.", written in dark ink.

Marcia Nussgart R.Ph.

Nugent
5225 Parks Hill Rd
#1626 N
Bethesda Md
20814



U.S. POSTAGE
PAID
KENSINGTON, MD
20895
JUL 20 99
AMOUNT

\$0.33
00034550-01

Mrs. Tipper Gore
Office of the Vice President
Room 200
Old Executive Office Building
Washington D.C. 20501

Attn: Audrey Haynes

20000/9333



Sarah -
Please
Acknowledge atm

REED SMITH

Reed Smith Shaw & McClay LLP

Sarah B —
Please take a
look at

June 9, 1999
this
NEG saw this
person at a
62k event.
ATH

Dear Audrey,
Re: DMERC / HCFA Policies
On Ventilators

Enclosed is background information on the DMERC and HCFA policies that would hurt sick respiratory care patients (past polio, ALS, emphysema etc.) unless changed as recommended in this material.

We understand that the Vice President is to be contacted on this issue, and Mrs. Gore was spoken to last week about the adverse impact of these policies on many disabled groups.

We would be pleased to speak with the Vice Presidents or the President's representatives on this very important and time sensitive issue.

Sincerely,
Phil Peter
(202-414-9258)

PITTSBURGH, PA
HARRISBURG, PA

WASHINGTON, DC
MCLEAN, VA

PHILADELPHIA, PA
NEW YORK, NY

PRINCETON, NJ
NEWARK, NJ

**BY HCFA TO SWITCH NPPV VENTILATORS FROM THE FREQUENT
AND SUBSTANTIAL SERVICING PAYMENT CATEGORY TO THE CAPPED RENTAL CATEGORY**

- HCFA's Newly Announced Proposed Policy Position Is That Noninvasive Positive Pressure Ventilators ("NPPV") Are Excluded From The Devices Requiring Frequent And Substantial Servicing Under Section 1834(a)(3)(A) Of The Social Security Act.
- This Position By HCFA Is Contrary To Long Standing Legal, Clinical And Factual Precedents.
- NPPV Ventilators Provide Needed Relief Through Frequent And Substantial Medical Treatment To The Sickest Of The Sick Respiratory Patients In Their Homes. These Patients Suffer From Neuromuscular Disorders (Post Polio, ALS, Etc.), Or Chronic Obstructive Pulmonary Diseases (Emphysema Etc.) Or Severe Sleep Disorders (Nocturnal Hypoventilation). Less Sick Patients Like Those Suffering From Sleep Apnea, Who Do Not Need Frequent And Substantial Servicing, Are Reimbursed Under The Capped Rental Category.
- In 1992 HCFA Coded NPPV Ventilators In The Frequent And Substantial Servicing Category, And For The Seven Years Since Then HCFA Has Reimbursed NPPV Ventilators In This Category.
- In 1993 Congress Codified HCFA's 1992 Coding Of NPPV Ventilators In The Frequent And Substantial Servicing Payment Category Through Amendments To The Social Security Act, Which In Section 1834 (a)(3)(A) Specifically Retained NPPV Ventilators In This Category.
- Further, The FDA's 1995 Guidance For Ventilators Determined That NPPV Ventilators Belong In A Separate And Distinct Category From Devices Falling In The Capped Rental Category.
- Also, The Clinical Criteria Agreed Upon In The 1998 Consensus Conference For Ventilators Reinforced And Substantiated The Long Standing Clinical Practice Of Providing Frequent And Substantial Servicing For NPPV Ventilator Users.
- Moreover, During The Entire Period From 1992 Until Two Months Ago, All Of HCFA's Actions Agreed With And Backed The Payment Of NPPV Ventilators In The Frequent And Substantial Servicing Category.
- In Late March 1999, For The First Time, HCFA Unveiled A Claim That They Had Miscoded NPPV Ventilators Seven Years Ago, Even Though HCFA Remained Silent On This Point During Congress' Actions in 1993, The FDA's In 1995, During The 1998 Consensus Conference, And During The Countless Reimbursements During This Time Period Of NPPV Ventilators In The Frequent and Substantial Servicing Category.
- Any Attempt At This Late Date For HCFA To Claim It Miscoded NPPV Ventilators Flies In The Face Of Contrary Positions By Congress, The FDA, And Long Established Clinical Guidelines And Practice.
- HCFA Is Getting Public Comments And Will Hold A Town Hall Meeting On This Miscoding Issue In Late June.
- Any Attempt By HCFA Following This Meeting To Switch NPPV Ventilators From The Frequent And Substantial Servicing Category To The Capped Rental Category Cannot Be Finalized Without Specific Approval By Congress.
- Targeted Communications By Key Members Of Congress To Appropriate HCFA And HHS Officials Are Needed I.e. Congressional Approval For Any Such Attempted Change In Reimbursement Category By HCFA Needs Congressional Approval.

Congress Must Ensure that the DMERC Medical Policy on NPPV Ventilators is Consistent with the Recommendations of the NPPV Consensus Conference

Clinical Concerns: The new DMERC Medical Policy governing the use of NPPV ventilators contains recently added criteria that are significantly different from the consensus recommendations of the clinical community.

- One important change appearing for the first time in the final DMERC draft would require physicians to write an "off-label" prescription for a prerequisite trial of two or three months using a different device before the doctor can prescribe an NPPV ventilator.
- The DMERCs' prerequisite trial requirement is inconsistent with the FDA's classification system and labeling determinations, as well as the consensus recommendations of the clinical community, the weight of the medical literature and HCFA's own requirements arising under the Medicare Carriers Manual.
- Another change removes coverage for those patients with carbon dioxide levels below 55, in conflict with the clinical community's recommendations.
- Additional concerns arise from a number of burdensome documentation requirements (e.g., physicians must sign-off on patient's compliance).

Procedural Concerns:

- The DMERCs did not include these important changes in the initial draft policy distributed to the public, and many of these changes will limit or eliminate coverage of medically necessary NPPV ventilators for Medicare patients.
- The new DMERC prerequisite requirement is invalid under HCFA's own guidelines, which require evidence that a particular alternative is safer, more effective, or more appropriate for a given condition and that such prerequisites are based on medical appropriateness, not on cost effectiveness.

Needed Action:

- HCFA and the DMERCs should reconcile their policies to conform in full, without exception, to the recommendations of the expert clinicians in the area of NPPV. The DMERC coverage policy should be revised to conform with the criteria developed during the NPPV Consensus Conference on February 4-5, 1998, as memorialized in the conferee's subsequent report and the comments the DMERCs received from the conference sponsor, the National Association for Medical Direction of Respiratory Care ("NAMDR").

:::ODMA\PCDOCS\WSH\130442\1

Respiratory Assist Devices - New Policy

A new policy on Respiratory Assist Devices (RAD) is included in the accompanying Supplier Manual Update. It is effective for dates of service on or after October 1, 1999.

The Health Care Financing Administration (HCFA) has proposed that the policy on Respiratory Assist Devices be effective October 1, 1999. Before implementing this policy, however, there will be an open meeting in the near future at HCFA in Baltimore to discuss the appropriate DME payment category for respiratory assist devices with bi-level pressure capability and with the backup rate feature. Please watch for the Federal Register notice of the meeting. HCFA hopes that all interested parties including the physician community, the supplier community and beneficiaries will be in attendance and that there will be a full discussion of the issue of the assignment of these devices into the capped rental payment category. It is HCFA's view that these devices are excluded from the class for items requiring frequent and substantial servicing in accordance with section 1834(a)(3) of the Social Security Act. HCFA will be accepting written comments on the appropriateness of the DME payment category for respiratory assist devices with bi-level pressure capability and with the backup rate feature that are received no later than 5 p.m. on June 15, 1999. Comments should be mailed to the following address:

Health Care Financing Administration
Division of Community Post-Acute Care
Attn: Joel Kaiser
C5-06-27
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments may also be submitted electronically to the following e-mail address:

jkaiser@hcfa.gov

E-mail comments must include the full name, address, and affiliation (if applicable) of the sender, and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments.

A special DMERC bulletin will be issued some time after the public meeting and prior to October 1, 1999, and will contain the determination of the payment category for each code and all applicable billing instructions.

Respiratory Assist Devices – New Codes

Several new codes have been established related to the new policy on Respiratory Assist Devices (RAD). Codes K0532 and K0533 are listed and defined in the policy which is included in the accompanying Supplier Manual Update. In addition, a related code has been established:

K0534 - Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)

This code is effective for dates of service on or after October 1, 1999.

K0534 describes a bi-level pressure device with backup rate feature when it is used with an invasive interface. (Code K0533 describes the same device when it is used with a noninvasive interface – e.g., a nasal or facial mask.) K0534 may be used only if the respiratory assist device is used with an invasive interface.

Accessories used with the K0534 will have the same utilization parameters as are described in the RAD policy for accessory codes K0187 - K0189.

Accessories Used with CPAP Devices

The new policy on Respiratory Assist Devices which is included in the accompanying Supplier Manual Update describes usual maximal amounts of accessories (K0183-K0189) which are expected to be medically necessary within a specified period of time when they are used with respiratory assist devices K0532 and K0533. Since these are the same accessories used with CPAP devices (E0601), for dates of service on or after October 1, 1999, the published amounts for these accessories will apply to their use with CPAP devices as well.

Heated Humidifier – New Code

A new code has been established for a heated humidifier that is used with a CPAP device (E0601) or a respiratory assist device (K0532, K0533, or K0534):

K0531 – Humidifier, heated, used with positive airway pressure device

This code is effective for dates of service on or after October 1, 1999. Code K0531 is in the Inexpensive or Routinely Purchased (IRP) DME payment category.

Published clinical evidence has not demonstrated that a heated humidifier provides a significant benefit compared to a nonheated humidifier. Therefore, if a K0531 humidifier is provided for use with a covered CPAP device or a covered respiratory assist device,

payment will be based on the allowance for the least costly medically appropriate alternative, K0268 (nonheated humidifier). This is a continuation of current DMERC policy.

Respiratory Assist Devices

HCPCS CODES:

The appearance of a code in this section does not necessarily indicate coverage.

Equipment:

- K0532 - Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
- K0533 - Respiratory assist device, bi-level pressure capability, with backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)

Accessories:

- K0183 - Nasal application device, used with positive airway pressure device
- K0184 - Nasal pillow/seals, replacement for nasal application device, pair
- K0185 - Headgear, used with positive airway pressure device
- K0186 - Chin strap, used with positive airway pressure device
- K0187 - Tubing, used with positive airway pressure device
- K0188 - Filter, disposable, used with positive airway pressure device
- K0189 - Filter, non-disposable, used with positive airway pressure device
- K0268 - Humidifier, non-heated, used with positive airway pressure device
- K0531 - Humidifier, heated, used with positive airway pressure device

HCPCS MODIFIER:

- ZX - Specific requirements found in the Documentation section of the medical policy have been met and evidence of this is available in the supplier's records.

BENEFIT CATEGORY: Durable Medical Equipment

REFERENCE: Coverage Issues Manual 60-9

DEFINITIONS:

As referenced in this policy, noninvasive positive pressure respiratory assistance (NPPRA) is the administration of positive air pressure, using a nasal and/or oral mask interface which creates a seal, avoiding the use of more invasive airway access (e.g., tracheostomy). It may sometimes be applied to assist insufficient respiratory efforts in the treatment of conditions that may involve sleep-associated hypoventilation. It is to be distinguished from the invasive ventilation administered via a securely intubated airway, in a patient for whom interruption or failure of ventilatory support would lead to imminent demise of the patient.

A respiratory assist device (RAD) without backup rate (K0532) delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface (such as a nasal or oral facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs (i.e., NPPRA).

A respiratory assist device (RAD) with backup rate (K0533) delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface (such as a nasal or oral facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs (i.e., NPPRA). In addition, it has a timed backup feature to deliver this air pressure whenever sufficient spontaneous inspiratory efforts fail to occur.

Accessories that are used to deliver air pressure to the patient's nose and/or mouth, and which do not involve an invasive delivery technique such as tracheostomy, are represented by codes K0183, K0184, K0185, K0186, K0187, K0188, K0189, K0268, and K0531. While these codes have represented accessories used with continuous positive airway pressure devices (CPAP), the same accessories are also used in the application of other forms of NPPRA therapy.

Polysomnography is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep for 6 or more hours with physician review, interpretation, and report. It must include sleep staging which is defined to include a 1-4 lead electroencephalogram (EEG), and electro-oculogram (EOG), and a submental electromyogram (EMG). It must also include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry.

FIO2 is the fractional concentration of oxygen delivered to the patient for inspiration. For the purpose of this policy, the patient's usual FIO2 refers to the oxygen concentration the patient normally breathes when not undergoing testing to qualify for coverage of NPPRA therapy. That is, if the patient does not normally use supplemental oxygen, their usual FIO2 is that found in room air.

COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this regional medical review policy, "reasonable and necessary" is defined by the following coverage and payment rules.

General:

The "treating physician" must be one who is qualified by virtue of experience and training in non-invasive respiratory assistance, to order and monitor the use of respiratory assist devices. Physicians who treat patients for other medical conditions may or may not be so qualified, and if not, though they may be the treating physician of the beneficiary for other conditions, they are not considered the "treating physician" for the administration of NPPRA therapy.

For the purpose of this policy, polysomnographic studies must be performed in a sleep study laboratory, and not in the home or in a mobile facility. It must comply with all applicable state regulatory requirements.

For the purpose of this policy, arterial blood gas, sleep oximetry and polysomnographic studies may not be performed by a DME supplier. A DME supplier is not considered a qualified provider or supplier of these tests for purposes of this policy's coverage and payment guidelines. This prohibition does not extend to the results of studies conducted by hospitals certified to do such tests.

If there is discontinuation of usage of a K0532 or K0533 device at any time, the supplier is expected to ascertain this, and stop billing for the equipment and related accessories and supplies.

Initial Coverage Criteria for K0532 and K0533 Devices (First Three Months):

For a respiratory assist device to be covered, the treating physician must fully document in the patient's medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.

A respiratory assist device (K0532, K0533) used to administer NPPRA therapy is covered for those patients with clinical disorder groups characterized as (I) restrictive thoracic disorders (i.e., progressive neuromuscular diseases or severe thoracic cage abnormalities), (II) severe chronic obstructive pulmonary disease (COPD), (III) central sleep apnea (CSA), or (IV) obstructive sleep apnea (OSA) (K0532 only) and who also meet the following criteria:

I) Restrictive Thoracic Disorders:

- A) There is documentation in the patient's medical record of a progressive neuromuscular disease (for example, amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (for example, post-thoracoplasty for TB), and
- B)
 - 1) An arterial blood gas PaCO₂, done while awake and breathing the patient's usual FIO₂, is ≥ 45 mm Hg, or
 - 2) Sleep oximetry demonstrates oxygen saturation $< 88\%$ for at least five continuous minutes, done while breathing the patient's usual FIO₂, and
- C) Chronic obstructive pulmonary disease does not contribute significantly to the patient's pulmonary limitation.

If all above criteria are met, either a K0532 or K0533 device (based upon the judgment of the treating physician) will be covered for patients within this group of conditions for the first three months of NPPRA therapy (see below for continued coverage after the initial three months). If all of the above criteria are not met, then K0532 or K0533 and related accessories will be denied as not medically necessary.

II) Severe COPD:

- A)
 - 1) An arterial blood gas PaCO₂, done while awake and breathing the patient's usual FIO₂, is ≥ 55 mm Hg, and
 - 2) Sleep oximetry demonstrates oxygen saturation $< 88\%$ for at least five continuous minutes, done while breathing oxygen at 2 LPM or the patient's usual FIO₂ (whichever is higher), and
- B) Prior to initiating therapy, OSA (and treatment with CPAP) has been considered and ruled out.

If all of the above criteria for patients with COPD are met, a K0532 device will be covered for the first three months of NPPRA therapy (see below for continued coverage after the initial three months). A K0533 device will not be covered for a patient with COPD during the first two months, because therapy with a K0532 device with proper adjustments of the device's settings and patient accommodation to its use will usually result in sufficient improvement without the need of a back-up rate. (See below for coverage of a K0533 device for COPD after 2 month's use of a K0532 device.)

If all of the above criteria are not met, K0532 and related accessories will be denied as not medically necessary. If K0533 is billed, but the criteria for a K0532 device are met, payment will be based on the allowance for the least costly medically appropriate alternative, K0532.

III) Central Sleep Apnea (i.e., apnea not due to airway obstruction):

Prior to initiating therapy, a complete facility-based, attended polysomnogram must be performed documenting the following:

- A) The diagnosis of central sleep apnea (CSA), and
- B) The exclusion of obstructive sleep apnea (OSA) as a primary cause of sleep-associated hypoventilation, and
- C) The ruling out of CPAP as effective therapy if OSA is a component of the sleep-associated hypoventilation, and
- D) Oxygen saturation $< 88\%$ for at least five continuous minutes, done while breathing oxygen at 2 LPM or the patient's usual FIO₂ (whichever is higher), and
- E) Significant improvement of the sleep-associated hypoventilation with the use of a K0532 or K0533 device on the settings that will be prescribed for initial use at home, while breathing the patient's usual FIO₂.

If all above criteria are met, either a K0532 or K0533 device (based upon the judgment of the treating physician) will be covered for patients with documented CSA conditions for the first

three months of NPPRA therapy (see below for continued coverage after the initial three months). If all of the above criteria are not met, then K0532 or K0533 and related accessories will be denied as not medically necessary.

IV) Obstructive Sleep Apnea (OSA):

- A) A complete facility-based, attended polysomnogram has established the diagnosis of obstructive sleep apnea, and
- B) A single level device (E0601, continuous positive airway pressure device) (CPAP) has been tried and proven ineffective.

If the above criteria are met, a K0532 device will be covered for the first three months of NPPRA therapy (see below for continued coverage after the initial three months). If K0532 is billed and these criteria are not met but the coverage criteria in the DMERC policy for Continuous Positive Airway Pressure System (CPAP) are met, payment will be based on the allowance for the least costly medically appropriate alternative, E0601.

A K0533 device is not medically necessary if the primary diagnosis is OSA. If K0533 is billed, payment will be based on the allowance for the least costly medically appropriate alternative, K0532 or E0601, if coverage criteria for those devices have been met.

Continued Coverage beyond First Three Months of Therapy:

Patients covered for the first 3 months of a K0532 or K0533 device must be re-evaluated to establish the medical necessity of continued coverage by Medicare beyond the first three months. While the patient may certainly need to be evaluated at earlier intervals after this therapy is initiated, the re-evaluation upon which Medicare will base a decision to continue coverage beyond this time must occur within 61 to 90 days of initiating therapy by the treating physician. There must be documentation in the patient's medical record about the progress of relevant symptoms and patient usage of the device up to that time. Failure of the patient to be consistently using the K0532 or K0533 device for an average of 4 hours per 24 hour period by the time of this 61-90 day re-evaluation would represent non-compliant utilization for the intended purposes and expectations of benefit of this therapy. This would constitute reason for Medicare to deny continued coverage as not medically necessary.

Aside from the above documentation in the patient's medical records, the following items of documentation must be obtained by the supplier of the device for continuation of coverage beyond three months:

- 1) A signed and dated statement completed by the treating physician no sooner than 61 days after initiating use of the device, declaring that the patient is compliantly using the device (an average of 4 hours per 24 hour period) and that the patient is benefiting from its use, and
- 2) A Medicare beneficiary statement completed by the patient no sooner than 61 days after initiating use of the device (see below).

If the above criteria are not met, continued coverage of a K0532 or K0533 device and related accessories will be denied as not medically necessary.

For Group II patients (COPD) who qualified for a K0532 device, if at a time no sooner than 61 days after initial issue and compliant use of a K0532 device, the treating physician believes the patient requires a K0533 device, the K0533 device will be covered if the following criteria are met:

- 1) An arterial blood gas PaCO₂, repeated no sooner than 61 days after initiation of compliant use of the K0532, done while awake and breathing the patient's usual FIO₂, still remains ≥ 55 mm Hg, and
- 2) A sleep oximetry, repeated no sooner than 61 days after initiation of compliant use of a K0532 device, and while breathing with the K0532 device, demonstrates oxygen saturation $< 88\%$ for at least five continuous minutes, done while breathing oxygen at 2 LPM or the patient's usual FIO₂ (whichever is higher), and
- 3) A signed and dated statement from the treating physician, completed no sooner than 61 days after initiation of the K0532 device, declaring that the patient has been compliantly using the K0532 device (an average of 4 hours per 24 hour period) but that the patient is NOT benefiting from its use, and
- 4) A Medicare beneficiary statement completed by the patient, no sooner than 61 days after initiation of the K0532 device.

If the above criteria for a K0533 device are not met, but are met for continued coverage of a K0532 device, payment will be based on the allowance for the least costly medically appropriate alternative, K0532.

Patients on a K0532 or K0533 Device prior to Effective Date of this Policy:

For patients in Groups I, II and III started on respiratory assist devices at any time (and in Group IV 3 months or less) prior to the effective date of this policy, the supplier must obtain the following for continued coverage:

- 1) A signed and dated statement from the treating physician declaring that the patient continues to compliantly use the device (an average of 4 hours per 24 hour period) and that the patient is benefiting from its use, and
- 2) A Medicare beneficiary statement completed by the patient.

For patients in Group IV started on K0532 devices greater than 3 months prior to the effective date of this policy, the requirements listed in the previous paragraph do not apply. Coverage will be continued. K0533 devices have not been covered for the treatment of patients in Group IV (OSA) even prior to the effective date of this policy and will continue to be denied as not medically necessary for this group of patients.

If the above criteria for continued coverage are not met, K0532 and K0533 devices and their accessories will be denied as not medically necessary.

Medicare Beneficiary Statement:

For continued coverage of a respiratory assist device the supplier must obtain a signed and dated statement from the beneficiary documenting that specified coverage criteria have been met. A suggested form for collecting this information is attached (whatever form is used must contain all of the questions contained on the attached suggested form). All of the questions on any Medicare beneficiary statement must be answered by the beneficiary, or a family member or caregiver, but may not be completed by the supplier. The completed statement must be obtained by the supplier prior to submission of further claims for a K0532 or K0533 device, at the times specified above. Responses reported on the statement must substantiate that the policy's criteria for continued coverage have been fulfilled. The responses must indicate that the beneficiary is currently still using the K0532 or K0533 device, using it for 4 or more hours per 24 hour period, that it has been used for at least 2 months at the time of the statement's completion, that the beneficiary has seen the treating physician within the month of statement completion and at least 61 days after initiating use of the machine, that the beneficiary plans to continue using a K0532 or K0533 device in the future, and that the person completing the statement was not the supplier.

Accessories:

The following table represents the usual maximum amount of accessories expected to be medically necessary:

K0183.....	1 per 3 months
K0184.....	2 per 1 month
K0185.....	1 per 6 months
K0186.....	1 per 6 months
K0187.....	1 per 1 month
K0188.....	2 per 1 month
K0189.....	1 per 6 months

Claims for more than the usual maximum replacement amount will be denied as not medically necessary unless the claim is accompanied by documentation which justifies a larger quantity in the individual case.

If a heated humidifier (K0531) is ordered for use with a covered respiratory assist device, payment will be based on the allowance for the least costly medically appropriate alternative (K0268).

CODING GUIDELINES:

HCPCS codes E0452, E0453, and K0194 are no longer valid for submission to the DMERC for dates of service on or after the effective date of this policy. If a respiratory assist device is used to apply NPPRA therapy that does not have the timed backup feature, bill using code K0532; if it has a timed

backup feature, bill using code K0533. For devices previously coded as E0452 or E0453, after the effective date of this policy, code E0452 as K0532, and if the E0453 is being used with a noninvasive interface to administer NPPRA therapy, code as K0533. For devices previously billed as K0194 (intermittent assist device with continuous positive airway pressure device [CPAP], with humidifier), use codes K0532 and K0268 to continue billing after the effective date of this policy.

DOCUMENTATION:

An order for all equipment and accessories must include the patient's diagnosis or an ICD-9-diagnosis code, be signed and dated by the treating physician, and be kept on file by the supplier.

All claims for K0532 or K0533 devices or their accessories must include an ICD-9-diagnosis code relating to the need for the device.

Proper use of the ZX modifier is discussed below. The ZX modifier must not be used on claims submitted to the DMERC until the required documentation has actually been obtained and entered into the supplier's files.

For Patients Placed on a K0532 or K0533 Device after the Effective Date of this Policy:

On claims for the first through third months, suppliers may add a ZX modifier to codes for equipment (K0532, K0533) only if all of the criteria for patients in Groups I-IV in the Coverage and Payment Rules section of this policy have been met. If the requirements for the ZX modifier are not met, the supplier may submit additional documentation with the claim to justify coverage, but the ZX modifier must not be used.

A ZX modifier should not be added to related accessory codes.

On the fourth month's claim (and any month thereafter), the supplier may only add a ZX modifier if all of the following additional documentation has been obtained for the supplier's files:

For all patients on a K0532 or K0533 device, the supplier must obtain:

- 1) The treating physician's signed and dated statement described in the Coverage and Payment Rules Section above, and
- 2) A Medicare beneficiary statement, completed and obtained according to the criteria stated in the Coverage and Payment Rules section.

In addition, for patients in Group II (COPD), when a K0533 device is being billed, the following additional documentation requirements must be met:

- 3) Repeat arterial blood gas PaCO₂, and
- 4) Repeat sleep oximetry,

both of which must meet the criteria described in the Coverage and Payment Rules section above.

For Patients Placed on a K0532 or K0533 Device prior to the Effective Date of this Policy:

- A) All patients on a K0532 or K0533 device 90 days or less prior to the effective date of policy:

For the first through third rental months' claims, a ZX modifier may be added if there is a physician's order in the supplier's file, and documentation in the patient's medical record of a covered diagnosis.

On the fourth rental month's claim (and any month thereafter), a ZX modifier may be added only if the supplier has obtained the documentation described in (1) and (2) of the previous section (treating physician and beneficiary statements).

- B) Patients in Groups I-III on a K0532 or K0533 device greater than 90 days as of effective date of policy:

A ZX modifier may be added only if the supplier has obtained the documentation described in (1) and (2) of the previous section (treating physician and beneficiary statements).

- C) Patients in Group IV (OSA) on a K0532 device greater than 90 days as of effective date of policy:

The ZX may be added to the K0532 code on these claims if there is a physician's order in the supplier's file, and documentation in the patient's medical record of a covered diagnosis. A ZX must not be added to claims for a K0533 used to treat Group IV patients (OSA).

For All Patients on Respiratory Assist Devices:

The physician and beneficiary statements must be kept on file by the supplier, but should not be sent in with the claim. The DMERC may request copies of this documentation at its discretion.

Clinical progress notes, hospital records and other elements of the patient's medical record must document support of the medical necessity and follow-up of the patient's NPPRA therapy. Relevant sections of the patient's medical record pertaining to NPPRA therapy must also be available to the DMERC upon its request.

When billing for quantities of accessories greater than those described in the policy as the usual maximum amounts, each claim must include documentation supporting the medical necessity for the higher utilization. This information must be attached to a hard copy claim or entered in the HAO record of an electronic claim.

Refer to the Supplier Manual for more information on orders, medical records, and supplier documentation.

EFFECTIVE DATE:

Claims with dates of service on or after October 1, 1999.

MEDICARE BENEFICIARY STATEMENT: Evaluation Of Respiratory Assist Device

Beneficiary Name: _____ Beneficiary Birth Date: ____ / ____ / ____

Beneficiary Telephone Number: (____) - ____ - ____

The Supplier May Not Answer Any Of The Following Questions.

- 1) Are you (the Medicare beneficiary) now using a machine that helps you take your breaths while you are asleep (separate from a machine that may be giving you oxygen or medicine)?

YES NO

- 2) How many hours a day do you usually use this machine?

_____ HOURS

- 3) How many months have you been using this machine?

_____ MONTHS

- 4) When did you last see the doctor who ordered this machine for you?

__ / __ / __

- 5) Will you keep using this treatment in the future?

YES NO

- 6) Did you (the Medicare Beneficiary) complete answers #1 - 6?

YES NO

If you did not answer these questions, who did and what is their relationship to you (for example, wife, husband, supplier of machine, etc.)?

Name: _____ Relationship: _____

beneficiary signature_____
date of signature

30042

Federal Register / Vol. 64, No. 107 / Friday, June 4, 1999 / Notices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-137]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection.

Title of Information Collection: Internal Revenue Service/Social Security Administration/Health Care Financing Administration Data Match and Supporting Regulations in 42 CFR Section 411.20-411.206.

Form No.: HCFA-R-137 (OMB# 0938-0565).

Use: The purpose of this collection is to save the Medicare program money. MSP is essentially the same concept known in the private insurance industry as coordination of benefits, and refers to those situations where Medicare assumes a secondary payer role (private insurance being the primary payer) for covered services provided to a Medicare beneficiary. It is HCFA's responsibility to implement the various Medicare Secondary Payer (MSP) provisions.

Frequency: Annually.

Affected Public: Federal Government, Business or other for-profit, Not-for-profit institutions, Farms, State, and Local or Tribal Government.

Number of Respondents: 276,251.

Total Annual Responses: 276,251.

Total Annual Hours: 1,051,722.

To obtain copies of the supporting statement and any related forms for the

proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 26, 1999.

John Parmigiani,

Manager, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, [FR Doc. 99-14122 Filed 6-3-99; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-1075-N]

Medicare Program; June 25, 1999 Public Meeting To Discuss the Payment Classification for Respiratory Assist Devices

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a public meeting regarding the appropriate durable medical equipment (DME) fee schedule payment category for respiratory assist devices (RADs) with bi-level pressure capability and with a backup rate feature. The meeting will provide an opportunity for physicians, suppliers, beneficiary advocates, and other interested parties to furnish information and raise issues about the payment classification for RADs. The meeting will address the following topics:

- Characteristics of the equipment.
- Whether the equipment needs frequent and substantial servicing in order to avoid risk to the patient's health.

DATES: The meeting is scheduled for June 25, 1999 from 9:30 a.m. until 3:30 p.m., eastern daylight time.

ADDRESSES: The meeting will be held at the Health Care Financing

Administration headquarters, in the auditorium, 7500 Security Boulevard, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT: Joel Kaiser, (410) 786-4499, or Gloria Knight, (410) 786-4598.

SUPPLEMENTARY INFORMATION:

Background

We are announcing a public meeting to provide an opportunity for physicians, suppliers, beneficiary advocates and other interested parties to furnish information and raise issues regarding the appropriate DME payment category for RADs with bi-level pressure capability and with a backup rate feature. The public meeting provides an open forum for addressing these issues. We anticipate participation by physicians, manufacturers, suppliers, national associations representing manufacturers and suppliers, the press, and other members of the public with an interest in issues relating to Medicare payment for RADs. We intend to discuss the information we have gathered and the general direction that we are moving concerning these topics. The format of the meeting will include an overview on RAD payment and coding topics.

For more detailed information regarding the pending HCFA coding decision on RADs, you may access one of the following Durable Medical Equipment Regional Carrier websites for the June bulletin:

REGION A: www.medicare-link.com

REGION B: www.astar-federal.com

REGION C: www.pgba.com

REGION D: www.cignamedicare.com

We will allow short (10-20 minutes) presentations by the public and our staff on these topics. The meeting will conclude with an open dialog during which the public may raise issues related to the topics discussed.

Individuals interested in making a presentation at the meeting must contact Joel Kaiser at (410) 786-4499 or via e-mail at JKaiser@hcfa.gov or Gloria Knight at (410) 786-4598 or via e-mail at GKnight@hcfa.gov no later than June 18, 1999. Individuals must identify which of the two topics they want to discuss during their presentation. Only a limited number of individuals will be able to make presentations because of time constraints. In an effort to assure that all viewpoints are represented, we will notify participants who are selected to make a presentation. We will not assign presentation times until after June 18, 1999.

While the meeting is open to the public, attendance is limited to space available. Individuals must register in advance as described below.

Registration

The Office of Professional Relations will handle registration for the meeting. Individuals may register by sending a fax to the attention of Martha Dixon at (202) 401-7438. At the time of registration, please provide your name, address, telephone number, and fax number.

Confirmation of receipt of your fax will constitute confirmation of your registration. Meeting materials will be provided at the time of the meeting.

If you have questions regarding registration, please contact Martha Dixon at (202) 358-1420.

We will accept written comments, questions, or other materials specifically dealing with the issue of the appropriateness of the DME payment category for RADs with bi-level pressure capability and with a backup rate feature that are received no later than 5 p.m. on June 15, 1999. Written submissions must be sent to: Health Care Financing Administration, ATTN: Joel Kaiser, Room C5-06-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 27, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

(FR Doc. 99-14140 Filed 6-3-99; 8:45 am)

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Application for Certification and Recertification as a Federally Qualified Health Center (FQHC) Look Alike, OMB No. 0915-0142—Revision

The Health Resources and Services Administration (HRSA) proposed to revise the application guide used by organizations applying for certification, or recertification as a Federally Qualified Health Center (FQHC) Look-Alike for purposes of cost-based reimbursement under the Medicaid and Medicare programs. The guide will be revised to reflect legislative, policy, and technical changes since May, 1997, the issuance date of the last guidance. Revisions will include reference to the Balanced Budget Act of 1997 which amended the statutory language pertaining to FQHC Look-Alikes to include the requirement that "an entity may not be owned, controlled, or operated by another entity", and the interpretation and implementation policy documents issued by the HRSA.

Estimates of Burden are as follows:

Form	Number of respondents	Responses per respondent	Hours per respondent	Total hour burden
Application	26	1	100	2,600
Recertification	148	1	20	2,960
Total	174			5,560

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Wendy A. Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: May 28, 1999.

Jane Harrison,

Director, Division of Policy Review and Coordination.

(FR Doc. 99-14230 Filed 6-3-99; 8:45 am)

BILLING CODE 4120-15-J

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C., Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, PAR 99-019—Non-Mammalian Organisms as Models for Anti-Cancer Drug Discovery.

Date: June 22-23, 1999.

Time: 8:30 am to 3:00 pm.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Wilna A. Woods, PHD, Deputy Chief, Special Review, Referral and Research Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, Rockville, MD 20852, (301) 496-7903.

Name of Committee: National Cancer Institute Special Emphasis Panel, Non-Mammalian Organisms as Models for Anti-Cancer Drug Discovery.

Date: June 23, 1999.

Time: 3:00 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

REED SMITH SHAW & MCCLAY LLP

1301 K Street, N.W.

Suite 1100 - East Tower

Washington, D.C. 20005-3317

Phone: 202-414-9200

Fax: 202-414-9299

HARRISBURG, PA McLEAN, VA NEW YORK, NY NEWARK, NJ PHILADELPHIA, PA PITTSBURGH, PA PRINCETON, NJ WASHINGTON, DC**TO:** Audrey Haynes Attn: Melissa**FROM:** Phil Peter**CO/FIRM:** Office of Mrs. Gore**PHONE:** (202) 414-9258**FAX NO.:** 456-6298**DATE:** June 9, 1999**TOTAL NUMBER OF PAGES INCLUDING COVER PAGE:** 19**ORIGINAL will follow via:** ☐ Regular Mail ☐ Overnight Delivery ☐ Messenger ☒ None**COPIES TO:**

Name	Firm/Company	Fax No.	Time Sent

NOTES:**IF YOU DO NOT RECEIVE ALL OF THE PAGES, PLEASE CALL Colleen AT (202) 414-9335.****CLIENT/MATTER:** 157848.20017**ATTORNEY NO:** 1384**TRANSMIT BEFORE:****TIME** ☐ AM ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ PM**IF A PROBLEM IS ENCOUNTERED WHEN SENDING THIS FAX, PLEASE CALL****TRANSMISSION TIME:**

AM PM

FINISH TIME:

AM PM

OPERATOR:**PRIVILEGED AND CONFIDENTIAL**

The information contained in this facsimile message is privileged and confidential, and is intended only for the use of the individual(s) or entity named above who have been specifically authorized to receive it. If the reader is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone and return all pages to the address shown above. Thank you.

The Honorable Thomas Bliley
Chairman, Committee on Commerce
United States House of Representatives
Washington, D.C. 20515-6115

Dear Chairman Bliley:

Thank you for your letter to the Administrator regarding Medicare's proposed change in reimbursement category for Non-invasive Positive Pressure Ventilation (NPPV) devices. I am responding on her behalf.

First, I want to make clear why HCFA has recently chosen to reexamine the payment category for NPPV devices. Our actions are intended to safeguard the health of Medicare beneficiaries, assure that quality of care remains high, and maintain the financial health of the Medicare program. Payments for NPPVs have grown dramatically in the last several years. From 1994 to 1998, payments have increased from \$4 million to \$126 million, with the projected expenditures for 1999 at \$165 million. As the IG has indicated to us in the past, major increases in expenditures for a category of services, if they are not caused by fraud or abuse, may be the result of overly generous Medicare payments.

Medicare makes rental payment on an indefinite basis for DME items in the "frequent and substantial servicing" category, while for items in the "capped rental" category, rental payments are made for up to 15 months with a maintenance payment made every 6-months thereafter. The higher total payments for items in the "frequent and substantial" servicing category also translate into higher costs for beneficiaries since they pay 20 percent of the rental payments.

Throughout our consultation with health professionals and DME representatives on the appropriate payment category classification for NPPV devices, it has become clear that the NPPVs themselves require little servicing. Changing the air filter seems to be the only frequent or regular servicing that these machines require. In addition, these machines have a fairly lengthy useful lifetime. Under the "frequent and substantial" servicing category, Medicare pays approximately \$600 a month for an indefinite period for NPPVs. Over a ten year period Medicare pays \$72,000 for a device that can be purchased for between \$3,000 and \$4,000.

If these items were moved to the capped rental category, HCFA would pay approximately \$4,800 in rental fees over a period of 15 months. Additional payments are also made for accessories such as face masks and air filters. After receiving the \$4,800 in rental payment for the devices, the supplier would then automatically begin to receive \$800 each year on an ongoing basis to maintain the equipment. Over the course of 5 years, the amount Medicare pays in maintenance fees would again equal the purchase price of the equipment.

Page 2 -- The Honorable Thomas Bliley

We recognize that the history of our decisions regarding payment for these items has not been consistent. For the reasons given above, we believe that it was warranted that we take a fresh look at what is the appropriate payment category for these devices. On June 25, 1999, HCFA held an open meeting to get input from the provider and supplier communities on this issue. Given the need to consider the issues and opinions raised at the June 25 meeting, the change in payment policy will not be implemented as proposed October 1, 1999. NPPVs will remain in the "frequent and substantial" servicing category until a final decision is made. The DMERCs are planning to proceed, however, with the NPPV coverage policy, as modified following recent discussions with the National Association for Medical Direction of Respiratory Care (NAMDRC).

Please find the responses to your specific concerns addressed below.

1. The policy regarding NPPVs is a DMERC policy and not a HCFA national coverage policy. Please see Attachment #1, a memo from Dr. Adrian M. Oleck, Medical Director for AdminaStar Federal, Inc., one of the four regional DMERCs to Ms. Penny Thompson, Director of the Program Integrity Group, HCFA. This memo addresses where DMERC policy is in agreement with the recommendations of the Consensus Conference and the instances where the policy and the recommendations diverge and the reasons for these differences. Also, please reference attachment #2 which is a compilation of the public's comments and the DMERC's response to them.

HCFA notes that there is no national requirement for local carriers or DMERCs to follow Consensus Conference statements. Our requirement is that DMERCs development of local coverage policies should be evidence-based and be reasonable and necessary for the care of the beneficiary.

2. Attachment #3 is a note from the staff of the Department's Office of the General Counsel's regarding HCFA's clarification of the appropriate payment category for NPPVs.
3. The following are examples of Medicare coverage guidelines that do not follow the recommendations of the indicated consensus conferences or consensus opinions of health professionals or expert clinicians:
 - o non-coverage of liver transplantation for individuals with hepatitis B ---American Liver Foundation Consensus Conference on Liver Transplantation for Hepatitis B
 - o patient selection criteria for Contigen injections for urine incontinence -- Consensus Opinion of the American Urological Association
 - o coverage of cryosurgery of the prostate -- Consensus Opinion of the American Urological Association
4. The following is a list of examples of HCFA payment policies that were changed in response to discovering incorrect payment classifications.
 - o In December of 1993, the ultra lightweight wheelchair (HCPCS code K0005) was moved

Page 3 -- The Honorable Thomas Bliley

from the capped rental fee schedule class to the fee schedule class for inexpensive or routinely purchased DME, allowing for purchase of these items. This change was made at the request of the DME industry, which argued that Medicare should allow purchase of these wheelchairs because the patients requiring this type of wheelchair were generally younger, more active, and would use the wheelchair for many years. From January, 1989, the initial year of the fee schedules, until December, 1993, all manual wheelchairs were classified as capped rental items.

- o In September of 1996, HCFA issued a ruling which clarified that orthotics that are attached to wheelchairs are wheelchair accessories and should be classified covered as DME. As a result of this ruling, several HCPCS codes for mobile arm supports attached to wheelchairs (codes L3964 thru L3974) were moved from the prosthetics and orthotics fee schedule class to the fee schedule class for inexpensive or routinely purchased DME. These devices were classified as orthotics from January, 1989 to September, 1996.
- o In July of 1989, at the request of manufacturers of wheelchair cushions, HCFA reviewed the data used to classify wheelchair codes E0183 and E0192 as capped rental items. The manufacturers felt that these items should be in the fee schedule class for inexpensive or routinely purchased DME. As a result of this review, HCFA was able to move these items to the fee schedule class for inexpensive or routinely purchased DME as the industry requested.
- o In March of 1995, tracheal suction catheters (HCPCS code A4624) were moved from the prosthetics and orthotics fee schedule class to the fee schedule class for DME supplies. This item, a supply used in conjunction with a suction machine or aspirator, was covered as a prosthetic device from January, 1989 to March, 1995.
- o In January of 1999, paraffin (HCPCS code A4265) was moved into the fee schedule class for DME supplies because HCFA determined that this item is a supply for the paraffin bath (code E0235). This code was paid on a reasonable charge basis from January, 1986 to January, 1999.
- 5. One example of a coverage policy that requires a trial that includes an "off-labeled" use of a drug or device as a precondition for coverage of another item or service is our requirement that patients with intractable epilepsy first try traditional medical therapy before we will cover vagal nerve stimulators. Traditional medical therapy for intractable epilepsy normally requires the off-labeled use of certain drugs.

The Medicare program provides coverage for the "off-label" use of drugs and devices approved by FDA. If a device approved by the FDA is used for indications other than those specified on its labeling, the decision as to whether or not the device is usually covered is made by our Medicare contractors who process Medicare claims; in this case, the DMERCs. Medicare's authority is based on section 1862(a) of the Social Security Act. Section 1862(a)(1)(A) provides in part..."Notwithstanding any other provisions of this title, no payment may be made under Part A or Part B for any expenses incurred for items or services which...are not reasonable and necessary for the diagnosis or treatment of illness

Page 4 -- The Honorable Thomas Bliley

or injury." "Reasonable and necessary" has been interpreted to mean items and services which are 1) safe and effective, 2) medically appropriate, 3) not investigational or experimental, and 4) not excluded from coverage by the statute. Our contractors make these decisions taking into consideration current authoritative medical literature, the advice of their medical consultants, and local standards of accepted medical practices.

6. FDA guidance documents are used by FDA to assist manufacturers in obtaining approval or clearance of products for marketing. The jurisdiction of FDA relates to the manufacture and sale of drugs, biologics and devices. Therefore, the guidance in FDA guidance documents is related to these issues. HCFA is a purchaser (payer) of health services and has concerns different from those of the FDA. Although FDA approval of drugs and devices is required for Medicare coverage, in many cases, Medicare coverage does not automatically occur with such FDA approval. HCFA also examines, through its assessment process: 1) relative effectiveness compared to other technologies for diagnosis and treatment, 2) application in general practice compared to application in controlled settings, 3) application to particular patient groups and facilities, and 4) statutory exclusions. FDA documents relating to clearance for marketing are not directed to HCFA policy formulation.
7. Attachment #4 consists of all of the records relating to the issue of whether NPPV devices do not require frequent and substantial servicing.

I hope this information answers the questions you have regarding NPPV devices. A similar letter is being sent to Chairman Upton. If you have any further questions, please contact Peter Hickman at (202)690-5950.

Sincerely,

Michael M. Hash
Deputy Administrator

Attachments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

JUL 23 1999

The Honorable Paul Wellstone
United States Senate
Washington, D.C. 20510

Dear Senator Wellstone:

Thank you for your letters to Secretary Shalala and the Administrator regarding Medicare coverage of augmentative and alternative communication (AAC) devices. We agree that these kinds of devices serve an important role in allowing persons with disabilities to communicate. I am responding on their behalf, and I regret the delay in this response.

Your letter addresses relevant points regarding the coverage of AAC devices and the basic issue that the Medicare program does not cover all services that may provide essential assistance or medically related benefits. For example, in general, the Medicare law excludes coverage of the following types of services: dental, eyeglasses, hearing aids, and self-administered drugs. In addition, the Medicare statute is so structured that, while all services must be medically necessary to qualify for coverage, medical necessity in itself does not qualify a service for coverage. Therefore, irrespective of advancements in technology, particular items may not qualify for coverage.

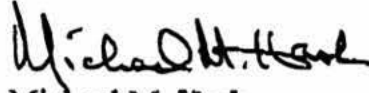
You allude to the possibility of Medicare covering AAC devices under the prosthetic device benefit. We are currently reviewing the underlying analysis of AAC devices again to see whether there is a basis for determining that they are an eligible benefit under Medicare. Specifically, based on our recent review of this matter, we believe that the possibility of coverage under the durable medical equipment benefit warrants further consideration. As part of this review, we have had discussions with the Office of the Assistant Secretary for Planning and Evaluation and other outside experts regarding the characteristics of the population that could benefit from these devices.

If HCFA determines this is an eligible benefit, we would then need to determine whether the benefit is reasonable and necessary for Medicare. This process for "reasonable and necessary" determination was published in a Federal Register notice on April 27. This notice is available on HCFA's website.

Page 2 - The Honorable Paul Wellstone

I hope this information is helpful, and I appreciate your interest in this issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael M. Hash". The signature is written in a cursive, somewhat stylized script.

**Michael M. Hash
Deputy Administrator**