

October 31, 2005

Paul J. Hughes, M.D.
Medical Director, DMERC Region A
TriCenturion, LLC
7909 Parklane Road, Suite 190
Columbia, SC 29223

Stacey V. Brennan, M.D.
Medical Director, DMERC Region C
Palmetto GBA
P.O. Box 100141, Mail Stop AG-250
Columbia, SC 29223

Adrian M. Oleck, M.D.
Medical Director, DMERC Region B
AdminaStar Federal
8115 Knue Road
Indianapolis, IN 46250

Donald D. Norris, M.D.
Interim Medical Director, DMERC Region D
c/o Mary H. Rheinecker, R.N.
CIGNA Government Services
2 Vantage Way
Nashville, TN 37228

Dear Drs. Hughes, Brennan, Norris and Oleck:

On behalf of the Power Mobility Coalition (PMC), a nationwide association of manufacturers and suppliers of motorized scooters and power wheelchairs, we submit these comments in response to the draft local coverage determination (LCD) for power mobility devices (PMDs) issued by the Durable Medical Equipment Regional Carriers (DMERCs). The draft LCD was promulgated to provide guidance in implementing the new National Coverage Determination (NCD) for Mobility Assistive Equipment (MAE). The PMC is very supportive of the new NCD which replaced the “bed or chair confined” criteria to the more practical functional ambulation standard. There are, however, several areas of concern with the LCD and the implementation of the NCD which we will discuss, in detail, below:

Indications and Limitations of Coverage and/or Medical Necessity

- Mobility for Mobility’s Sake Should be Included as a Qualifying MRADL

At CMS’ Special Open Door on the proposed NCD changes, clinicians, beneficiaries, suppliers, and manufacturers alike called for mobility – the act of being able to get from one place to another – to be considered a MRADL. Some severely disabled beneficiaries will not be able to perform any ADLs specified under the NCD, yet it would be unjust to exclude such individuals from having access to life and health enhancing MAEs.

- Qualifying MRADLs Should Not Be Limited to “In the Home”

The “in-home” restriction severely impedes on the health and independence of people with disabilities, as it essentially confines people to the four walls of their homes and does not take into account the need for beneficiaries to access their physician’s office, pharmacy, grocery store, bank or place of worship, which are all activities of daily living. Any new guidelines must reflect the functional assessment of a beneficiary’s needs both inside AND outside of the home (as indicated in IWWG recommendations). By failing to remove this restriction, needy beneficiaries will continue to be denied access to necessary mobility products and services. As a

result, the PMC strongly urges CMS to adopt coverage guidelines that focus on a functional based clinical evaluation devoid of any “in-home” restriction.

In addition, Medicare beneficiaries who leave the home on a frequent basis or for a lengthy duration are in jeopardy of losing their homebound status, and therefore, access to Medicare home health services (both skilled and custodial). Medicare beneficiaries should not be penalized and voluntarily “incarcerated” in their homes in order to retain their homebound status if they have the opportunity, through access to power mobility, to regain their independence and freedom. Both anecdotal and empirical evidence proves that Medicare beneficiaries with power mobility products and services lead more active, engaged, and as a result, healthier lives. As such, beneficiaries with a skilled nursing need should not be denied their rightful home health benefits if they are able to leave the home as the result of power mobility technology. Moreover, the “in-home restriction” policy is contrary to the letter and the spirit of Bush Administration goals like the New Freedom Initiative and Welfare to Work programs.

- The RESNA-Certified Assistive Technology Provider (ATP) Requirement is Unrealistic

There are simply not enough RESNA-certified ATPs to perform the comprehensive evaluation of the beneficiary required by the draft LCD. One PMC supplier-member who serves the metropolitan New York-New Jersey area could only identify one ATP that could perform such an assessment. This scarcity will be exacerbated in rural or underserved areas, leading to possible access issues for qualified beneficiaries in these areas.

The PMC asserts that an evaluation by a clinician, either an occupational therapist (OT) or physical therapist (PT), along with the face-to-face examination by the health practitioner will be sufficient to ensure eligibility and proper placement in the appropriate MAE. Further, assessments made by licensed OTs or PTs must be considered by CMS contractors, even if the clinician is reimbursed by the supplier. Such licensed practitioners would lose their ability to practice if they failed to use proper protocol and standards for making assessment and recommendations for MAEs.

- The Role of a Caregiver Should Not Be Determinative of MAE Eligibility

The presence of a caregiver should have no bearing on a beneficiary’s medical necessity for a MAE. While a caregiver can be instrumental in helping a person with limited or compromised disability perform MRADLs and remain independent, a beneficiary’s medical diagnosis and condition does not change because a caregiver is present. At best, the role of a caregiver should be considered among the environmental factors when determining MAE eligibility. Even in this context, the age and capability of the caregiver should be considered to ensure a proper assessment of the role the caregiver can play in the ability of the beneficiary to conduct their MRADLs.

- Least Costly Alternative Not Always the Best Alternative

The draft LCD states that High Activity, Standard Plus Use and General Use power wheel chairs will be paid at the least costly alternative. The rationale for this statement is that these products contain additional features that are not needed “in the home.” Under the draft LCD, claims for

these power wheelchairs will be down coded to a Standard Use power wheelchair. We believe that the application of the “least costly alternative” as used in this provision and through out the LCD is inappropriate and will deny access to medically necessary equipment.

The Standard Use power wheelchair is designed for intermittent use only and would not meet the needs of an individual who uses the power wheelchair for extended periods. For example, the Standard Use power wheelchair would meet the needs of an individual who uses the wheelchair for limited periods to move to general areas, but not for someone who is a continuous user and spends a significant amount of time in the wheelchair each day to accomplish their MRADLs. The draft LCD also suggests that the only criteria that will qualify a patient for a Standard Plus use wheelchair is a weight over 220 pounds. This lone criterion is inappropriate and should not be the basis for determining coverage. The Standard Use power wheelchair is not designed for regular use regardless of the patient’s weight.

Moreover, while the Standard Plus Use, High Activity and General Use power wheelchairs contain features that may make them useful outside the home, many of these same features may also be necessary for use in the home. The Standard Use product is designed for flat smooth surfaces only and cannot accommodate any obstacles. The Standard Use power wheelchair cannot accommodate changes in floor surfaces such as carpeting or tiles, for example. Focusing on these added features alone is an arbitrary application of least costly alternative principles. The key inquiry should be the medical needs of the patient and whether he or she requires extended use of the wheelchair. If the medical opinion of the treating physician is that the patient needs a power wheelchair in a category other than Standard Use, the product prescribed as medically necessary should be covered and paid appropriately.

The PMC is concerned that the result of only considering the needs inside the home will either be that beneficiaries will attempt to use these devices in inappropriate environments, or be essentially confined to their homes. While it may be cost intuitive to the Medicare program, we are concerned that overall risk and safety of the beneficiary, when provided a least costly alternative, will not be taken into consideration in such cases where a beneficiary may attend activities outside their home.

We raise the same concerns with respect to power operated vehicles (POVs). The draft LCD limits coverage to Standard Use POVs for patients under 220 pounds. As we noted above, the patient’s weight should not be what determines coverage. The Standard Use code category for POVs is intended for intermittent use only. This product is inappropriate for someone who requires extended use of the POV, regardless of his or her weight.

Documentation Requirements

- A Certificate of Medical Necessity (CMN) Should Certify Medical Necessity for MAEs

The PMC recommends that any documentation requirement be incorporated into a revised CMN that includes the eligibility criteria and algorithmic process that is set out in the NCD. Congress authorized that a supplier may distribute a CMN to a physician and such document, defined by Congress and developed by CMS, has long provided clarity and consistency to Medicare participants concerning the eligibility for the power mobility benefit. The treating physician

completes the CMN and is in the best position to assess patient need and certify that the beneficiary meets the functional ambulation standard. The physician's standing is strengthened by the face-to-face examination requirement prior to submission of a power mobility claim

Suppliers should be able to submit the physician signed and completed CMN to the Medicare program with the clear and unequivocal expectation that, if not fraudulent, such documentation establishes medical necessity. At a minimum, CMS could create a “scripted” prescription - containing all elements of the NCD – that can provide objective criteria in which suppliers can reasonably rely upon to demonstrate beneficiary eligibility.

- Draft LCD Requires Suppliers to Make Clinical Judgments as to What Satisfies Eligibility Under a Claim

Any comprehensive change to the LCD must include a clear documentation requirement that provides clarity and consistency to beneficiaries, physicians, and suppliers participating in the Medicare program. Unfortunately, the LCD fails to provide this level of specificity and clarity. The LCD urges the reliance on medical chart and progress notes, and leaves it up to the supplier to determine what parts of these records are “pertinent” to supporting the eligibility of the beneficiary. Medical charts and progress notes are not uniform, often fail to be comprehensive and sometimes fail to indicate the ambulatory status of patient. Moreover, suppliers who lack medical training should not be put in the position to make such determinations over the sufficiency of medical documentation.

The PMC recommends the creation of an advisory committee, comprised of interested stakeholders - including beneficiaries, health practitioners, clinicians, suppliers and manufacturers, to develop clear and consistent documents and documentation guidelines.

- 30-Day Timeline Should Be Extended to at Least 90-120 Days

The draft LCD requires that a DME claim be submitted within 30 days of the face-to-face examination. Such a short timeframe would make it difficult for many beneficiaries, with appropriate needs, to access power mobility equipment. In many instances, physicians have to wait until the beneficiary sees an occupational or physical therapist before knowing what type of power mobility to prescribe. It would be difficult for a beneficiary to be able to schedule a physician visit and a subsequent visit with a rehabilitation specialist all within a 30-day time frame. Meeting this short time frame will be especially problematic in rural and underserved areas.

To better promote efficiency and ensure that beneficiaries have the requisite time for all necessary examinations, the PMC recommends that the 30-day timeframe under the draft LCD be extended to at least 90-120 days with exceptions carved out for circumstances that necessitate a longer time frame.

- Suppliers Should be Reimbursed for Emergency and On-Going Assistance Services for Wheelchairs

The policy article that accompanies the draft LCD notes that suppliers’ reimbursement “includes support services, such as emergency services, delivery, set-up, education, and on-going

assistance with use of the wheelchair.” Support services such as delivery, set-up and education have long been included as part of the reimbursement rate. Costs for emergency services and on-going assistance, however, have never been rolled into the cost of the chair. Moreover, the draft LCD fails to describe what exactly constitutes an “emergency service” or “on-going assistance.” Such services could add hundreds of dollars to the price of the chair, especially if the beneficiary lives in a high-cost area. Suppliers cannot and should not be responsible for any or all repairs for the life of the chair. At a minimum, the LCD should provide specific examples of what constitutes an “emergency” or “on-going assistance” so that suppliers can know exactly what their responsibilities and reimbursement associated with the maintenance of the wheelchair.

We appreciate your time and consideration of these issues and look forward to working with CMS and the power mobility community to address these concerns.

Sincerely,

Eric W. Sokol
PMC Director

Stephen M. Azia
PMC Counsel