TESTIMONY BEFORE THE UNITED STATES SENATE COMMITTEE ON FINANCE

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Chairman Grassley and Members of the Committee: Good morning. Thank you for the opportunity to be here today to discuss how to ensure that individuals with disabilities receive appropriate and necessary wheeled mobility devices, while guarding against waste and abuse of federal Medicare funding.

My name is Laura Cohen. I am a physical therapist and hold a Ph.D. in Rehabilitation Science from the University of Pittsburgh. I am also credentialed by the Rehabilitation Engineering & Assistive Technology Society of North America (RESNA), as an assistive technology practitioner.

My experience includes three distinct professional activities spanning a period of 17 years: direct and supervisory clinical service; policy development; and claims review. I have provided direct clinical physical therapy services and have supervised other professionals and students throughout my career. These services included evaluations and recommendations for medically necessary seating and mobility systems. As part of these duties, I prepared documentation required for equipment to be funded by Medicaid, Medicare and numerous insurers. I worked to develop "medical necessity" guidelines for specialty manual and power wheelchairs for the Pennsylvania Medicaid program; participated in the development of a multi-agency and multi-task assistive technology services delivery program in Tucson, Arizona and proposed a similar model assistive technology services delivery program for an administrative region of the Department of Veterans Affairs. For the past six years, I have served as a second level reviewer of durable medical equipment claims for the contractor that administers the military medical TRICARE program in 16 states.

I believe my experience with these diverse medical benefits programs gives me a broad perspective regarding durable medical equipment evaluation and recommendation practices.

I am pleased to have this opportunity to discuss with you the policies, methods and procedures that I employ as a physical therapist and assistive technology consultant to ensure that individuals with need for power wheelchairs receive equipment that meets their immediate and future anticipated mobility needs in a cost effective manner.

My Testimony Does Not Address Medicare Fraud

My testimony will include suggestions for modifying the Medicare process to ensure needed services are provided while protecting against waste and abuse of resources. By contrast, my testimony will not address Medicare fraud. Fraud, in my opinion, is not impacted by regulation or the claims review process. Neither will it control falsification of claims and documents or other fraudulent acts. However, much can be done to ensure that Medicare only pays for the most medically necessary, appropriate, and cost effective devices.

My Role As A Second Level Reviewer

I was hired by a TRICARE contractor to review the medical necessity and appropriateness of requests for items of durable medical equipment that exceed $1,500. These equipment requests include items such as seating systems, manual and power wheelchairs, scooters and vehicle lifts. These categories of devices represent multiple Healthcare Common Procedure Coding System (HCPCS) codes. This means that there

are numerous individual device choices within each code. More specifically, it is my job to determine whether the clinical data submitted, in support of the funding request, identifies the recipient's current and reasonably anticipated future medical needs; and whether the device requested represents the most cost effective alternative to meet those needs.

My review functions arise as part of a prior authorization (prior approval) procedure, which is utilized by TRICARE. Prior authorization also is commonly used by insurers and Medicaid programs. It requires the recipient or provider to submit documentation in advance of delivery of the item or service. Only if the documentation is complete and the recommendation is well justified is the request approved. If gaps in the data exist, or if the data raise questions about the recommendation, the reviewer can insist that additional information or explanation is provided before any financial obligations or commitments are created.

By contrast, Medicare is a claims based system, in which the item must be delivered or the service provided before a claim for payment is submitted. This procedure does not utilize a skilled reviewer, and it does not facilitate correction of documentation related flaws or analytic gaps.

Despite these procedural differences, TRICARE defines "durable medical equipment" in a manner that is not materially different from the Medicare definition of this phrase. Also, TRICARE's definition of "medically necessary" is substantively equal to the Medicare standard of "reasonable and necessary."

For DME requests for power wheelchairs, the TRICARE Central Region requires the following written documentation for review and prior authorization: a signed

prescription from a physician; an order that specifies and justifies the equipment; and a price quote with HCPCS codes. In addition, there may be other supporting documents submitted including physician notes, test results, and therapy reports. Presently, there are no guidelines that identify the specific data that must be assessed or reported.

In addition, there are no specific qualifications with regard to the professionals who can submit documentation in support of a manual or power wheelchair funding request. One constraint on imposing requirements for specific professionals as data sources is the need for TRICARE recipients in rural areas to have adequate access to covered items and services.

When I perform a review of documentation submitted in support of a manual or power wheelchair funding request, I examine three critical components of the assessment and reporting process: the physical evaluation; the assessment of the individual's environment; and the specifications of the technology being requested for payment. As both a clinician and claims reviewer, I find these three components must be present for the wheelchair funding documentation to be complete and to adequately explain the basis for the device being requested. As an aside, copied physician notes not specific to the wheelchair request and certificates of medical necessity are not particularly useful to me.

Based on the information provided, I make one of four recommendations: I approve the request; I suggest an alternate device; I recommend further assessment to collect needed missing information; or I deny the request. My recommendation then goes to the regional Medical Director for final determination.

OBSERVATIONS

The Clinical Decision Making Process

A clinical evaluation of an individual's physical, functional and environmental characteristics is the cornerstone of the inter-related decision making processes in which an individual's mobility needs are documented. The average licensed clinician, given a list of required elements, would be skilled to fill this role. However, specialty knowledge of the plethora of equipment options and features is required to link an individual's mobility needs to specific equipment features. In addition, a supplier with specialty knowledge is needed as an integral member of the team to link equipment features to a specific device that will work in an individual's environment. The outcome of this team process is a recommendation for a manual or power wheelchair system that is appropriate to meet the individual's present and anticipated mobility needs. This information in total is submitted for third party funding approval. When properly documented, this process leads to efficient decision making within the third party funding process.

My observation is that the documentation I review frequently lacks information and rationale to justify the request. Therefore I often am unable to make a clinical decision of medical necessity, appropriateness or cost effectiveness without requesting additional information.

Clinical Assessment and Reporting Guidance are Needed

One solution to assessment or documentation omissions is for funding programs such as Medicare to adopt coverage criteria that spell out the data required to be assessed and reported as part of the decision making process. The Medicare coverage policies for

"lower limb prostheses" and "speech generating devices" are good examples of such coverage policies [posted at: http://www.cignamedicare.com/dmerc/lmrp_lcd/LLP.html and http://www.cignamedicare.com/dmerc/lmrp_lcd/SGD.html]. Each of these guidelines state clear expectations regarding clinical assessment and data reporting.

Clearly stating the assessment and data reporting expectations provide several benefits. The publication of assessment and reporting guidelines helps to ensure all necessary data have been gathered; relevant topics addressed and documented to support funding requests. Of equal importance, a clinician with general experience will be able to recognize when collaboration with a specialist is needed.

A Means to Identify Skilled Professionals is Needed

There is a documented shortage of skilled and trained professionals competent to evaluate, recommend and supply seating and mobility devices. It is very difficult to identify qualified and knowledgeable clinicians and suppliers. Another way to improve the quality of assessment and documentation supporting manual and power wheelchair funding requests is to focus on the professionals who are involved in the data gathering and reporting process.

In efforts to help identify skilled assistive technology professionals RESNA has instituted voluntary credentialing programs for providers who have demonstrated a combination of education, experience and minimal competency. There are three credentials available: the ATP for Assistive Technology Practitioner that includes clinicians such as physicians, occupational and physical therapists; the ATS, for Assistive

Technology Suppliers, and the RET for Rehabilitation Engineering Technologists and professionals.

As of March 31, 2004 there are 2169 credentialed professionals (1328 ATPs, 817 ATSs, and 24 RETs). By and large, despite the increasing number of credentialed clinical practitioners, this voluntary credential has not been widely pursued by the clinical community. Although it is not a perfect test of wheelchair and seating assessment skill, it is the only existing means by which clinicians interested and experienced in these areas of practice can distinguish themselves.

In efforts to identify skilled suppliers to provide DME for Medicaid recipients, approximately ten states are considering consumer protection legislation that requires suppliers to employ RESNA credentialed staff (ATSs) for the delivery of seating and mobility equipment. One state (Tennessee) has adopted consumer protection legislation for wheeled mobility. In response, there has been a rise in the number of credentialed suppliers in efforts to meet this service demand.

Although numbers are small right now, the RESNA credentialing program serves as a vehicle for which clinicians and suppliers that are specialists in the area of assistive technology can be identified. While the RESNA credentialing program is currently entry level, it is a beginning and could be enhanced. No other specialty certification process exists for this field.

Further consideration should be given to the idea of specialty certification and/or credentialing for individuals involved in the decision making process for manual and power wheelchairs. These discussions should occur with the American Occupational Therapy Association (AOTA), American Physical Therapy Association (APTA), and

RESNA so that there is a higher degree of confidence regarding the skill and experience of those involved in this decision making process.

Functional Classifications and Coding

The CMS coding and coverage policy with regard to wheeled mobility has not kept pace with changes in technology. Stated most generally, coding for manual and power wheelchairs focuses primarily on the chair's weight, and gives inappropriate attention to other important equipment characteristics. In my opinion, wheeled mobility lends itself to a policy similar to that established by CMS for lower limb prostheses (LLP). Sophisticated technology is supported by a coding scheme that is linked to functional classifications. The LLP policy acknowledges different levels of function of beneficiaries first, and then based on clinical indicators, links functional classifications to HCPCS codes. Wheeled mobility policy lends itself to a similar classification system that is based on an individual's physical ability, environmental considerations, and mobility potential. If the technology is adequately defined by HCPCS codes, then appropriate payment for the product provided should occur. Moreover, if there is a clear Medicare coverage policy, the review of medical need becomes objective, consistent, and predictable.

Prior Authorization and Peer Review

Given the sophistication of wheeled mobility technologies, certain devices should be subjected to a prior authorization process including review by an independent clinical peer reviewer. Determining what will be paid prior to purchase will add much needed

predictability to the system. As noted previously, prior approval is the standard operating procedure for TRICARE, Medicaid and many insurers. A system consisting of: (a) clear coverage guidance; (b) focus on skilled decision makers and skilled reviewers; and (c) a prior authorization procedure, has the potential to eliminate both CMS and Congressional concern about waste and abuse regarding Medicare manual and power wheelchair funding.

A true prior authorization process differs from the current Advanced Determination of Medical Coverage (ADMC) process. The latter does not guarantee authorization of payment. It is designed only to determine establishment of medical need. With the ADMC process if complete documentation for clinical decision making is not included the application is denied. It leaves the consumer and supplier in a position where the provision of supplemental documentation that may support a request cannot be submitted for another 6 months.

I am not suggesting that, nor is it necessary, for Medicare to re-design its entire administrative structure to accommodate a prior authorization procedure. To the contrary, prior authorization for selected items, such as certain manual and power wheelchairs is all that is proposed here.

RECOMMENDATIONS FOR SAFEGUARDING CMS SYSTEM

In order to make meaningful recommendations for safeguarding the CMS system, it is important to outline the key elements in the overall process. Any gap or inadequacy in the process can cause the system to fail in its efforts to curtail waste and abuse.

The foundation for the process requires adequate coding, coverage and appropriate payment. These elements are truly the foundation the rest of the process is built upon. It is also important to recognize that, historically, policy implemented by CMS is commonly used as a model for other third party payors.

In my opinion, the committee should look at the existing CMS policy for the lower limb prosthesis as a model for safeguards in the present system for manual and power wheelchairs. I advocate for a new wheeled mobility policy that emulates the lower limb prosthesis coverage policy. This policy would provide for wheeled mobility technology that is: reasonable and necessary for the diagnosis or treatment of illness or injury; and required to improve or augment functioning due to an unmet functional mobility need.

A **new coverage policy** would incorporate the development of a functional classification system that would be linked to a revised coding scheme. Corresponding clinical indicators would be employed to adequately categorize various mobility technologies. Unique codes must be established that recognize differences in technology and keeps pace with the development of new technologies. Distinct coding also provides for payment to be appropriate for the actual level of technology being provided.

The medical equipment industry (Power Mobility Coding Task Force under the auspices of AAHomecare) submitted a power wheelchair code application to CMS in

March 2002 and again in March 2003. The proposal reflects a system consistent with this recommendation. I suggest that this proposed coding scheme be adopted and implemented in a timely fashion. [Exhibits A, B and C]

Similarly, when addressing the issue of knowledgeable professionals I would direct the Committee to existing CMS policy regarding Speech Generated Devices (SGD). For SGDs, Medicare recognized that the speech-language pathologist is the professional best able to make determinations of medical need. Presently, the SGD coverage policy represents the only Medicare covered item or service for which a non-physician is permitted to make this determination. Manual and power wheelchairs should be another. For seating and mobility systems, it is far more likely that the most knowledgeable professional is the occupational or physical therapist. A coverage policy that reinforces the role of the most knowledgeable professional will increase the overall quality and credibility of the recommendations being presented to Medicare for funding. Although I have proposed a re-evaluation of the physician's dominant role in the data gathering and decision making process, I advocate a procedure in which the physician remains involved.

Procedurally, I would encourage a clear **requirement for written documentation** that will be useful and sufficient in making clinical decisions about medical necessity and appropriateness. Minimally this should include the elements of the physical evaluation, environmental considerations, technology specification and rationale for selection. Documentation would not need to be submitted with a claim; however, would need to be in the supplier's files and subject to preauthorization review or post payment audit. The data to be submitted for payment should include information about

the patient's diagnosis code, functional level, environmental mobility needs, equipment specifications (manufacturer and model) with technology codes and Medicare's Fee Schedule. This information, when signed by the physician will serve as the prescription and request.

This documentation will be submitted to Medicare as part of a limited or focused prior authorization process. A **prior authorization process, utilizing a qualified clinical peer reviewer**, who determines whether the documentation is complete and the recommendation adequately justified, should be limited to certain sophisticated technologies for those beneficiaries with the most complex functional needs. These beneficiaries happen to be the smallest group in the Medicare population. This system will protect consumers and ensure that they acquire the most appropriate equipment that will meet their mobility needs. A preauthorization and analogous **post payment audit process** will facilitate procedural objectivity, predictability and consistency.

In closing, I believe it is crucial in the development of process requirements, regulatory guidelines, and other important policy development aimed at reducing waste and abuse that the patient is not left behind. It is imperative that access to the technology that allows for independence and enhances the quality of life not be denied or reduced. Every effort must be made to ensure access to technology and maintain quality outcomes for the healthcare dollars spent. Ensuring that patients can perform basic activities of daily living in their homes and in their community as well as access to community services is paramount.

Lastly, what could be useful is having an advisory committee provide guidance on these issues. A committee would need representation from the clinical, supplier and industry communities and include a consumer as well.

I would like to offer my assistance to Congress and CMS as you continue to address these important issues. Thank you for this opportunity to express my opinions.

RESOURCES

Region D DMERC Local Medical Review Policy for lower limb prostheses (L11453)
http://www.cignamedicare.com/dmerc/lmrp_lcd/LLP.html

Region D DMERC Local Medical Review Policy for speech generating devices (L108)
http://www.cignamedicare.com/dmerc/lmrp_lcd/SGD.html

Rehabilitation Engineering and Assistive Technology Association of North America
http://www.resna.org

Georgia Department of Community Health Division of Medical Assistance policy and procedures for durable medical equipment services
https://www.ghp.georgia.gov/wps/output/en_US/public/Provider/MedicaidManuals/Durable_Medical_Equipment_Services_DME_01_2004.pdf