

1111 North Fairfax Street
Alexandria, VA 22314-1488
703 684 2782
703 684 7343 fax
www.apta.org

Officers

Paul A. Rockar Jr, PT, DPT, MS
President

Sharon L. Dunn, PT, PhD, OCS
Vice President

Laurita M. Hack, PT, DPT, PhD,
MBA, FAPTA
Secretary

Elmer R. Platz, PT
Treasurer

Susan R. Griffin, PT, DPT, MS,
GCS, RP
Speaker of the House

Stuart H. Platt, PT, MSPT
Vice Speaker

Directors

Jeanine M. Gunn, PT, DPT

Roger A. Herr, PT, MPA, COS-C

Matthew R. Hyland, PT, PhD, MPA

Kathleen K. Mairella, PT, DPT, MA

Sheila K. Nicholson, PT, DPT, JD,
MBA, MA

Carolyn M. Oddo, PT, MS, FACHE

Mary C. Sinnott, PT, DPT, MEd

Nicole L. Stout, PT, MPT,
CLT-LANA

Susan L. Whitney, PT, DPT, PhD,
NCS, ATC, FAPTA

Chief Executive Officer

J. Michael Bowers

Combined Sections Meeting

February 4-7, 2015
Indianapolis, IN

July 25, 2014

Submitted Electronically

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

ATTN: CMS-6050-P

RE: The American Physical Therapy Association's Response to the Proposed Rule: *Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items*

Dear Ms. Tavenner:

On behalf of our 88,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the *Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items* proposed rule, released on May 22, 2014. We respectfully provide the following comments:

Rehabilitative Services

Physical therapy services encompass the diagnosis of, interventions for, and prevention of impairments, activity limitations, and participation restrictions related to movement, function and health.¹ Physical therapists are licensed health care professionals who diagnose and manage movement dysfunction and enhance physical and functional status in all age populations. Physical therapists are qualified to provide rehabilitative and habilitative services, these services are often a less costly, yet effective, treatment for conditions such as back pain, osteoarthritis and incontinence.

¹ *Interactive Guide to Physical Therapist Practice* by American Physical Therapy Association. 2003. ISBN: 978-1-887759-87-8. DOI : 10.2522/ptguide.978-1-931369-64-0

APTA is committed to advancing the safety and quality of healthcare and we are eager to work with CMS in promoting access to appropriate health care services and supplies in the current environment of fiscal constraints. We support the reduction of fraud and abuse in the health care industry and we educate and provide numerous resources to our membership on ethics and compliance in practice. At the same time, in this current environment of practitioner shortages, it is imperative that vulnerable populations, such as the aging population, have timely access to the appropriate health care services and supplies that they medically require. APTA commends the Secretary on her efforts to curtail fraud and abuse with DMEPOS usage. We also realize that these supplies must be subject to certain constraints to control health care expenditures. However, APTA is concerned that certain proposed changes could impede or delay access to timely medically necessary care, decrease patient safety, possibly increase the costs of care and create excessive administrative burdens to the provider and CMS or its contractors. To expand upon these concerns, please consider the following:

Administrative and Technical Issues Regarding Prior Authorization

Before implementing prior authorization for DMEPOS, it is essential that CMS have the infrastructure in place to properly and efficiently process these requests so that patient care is not jeopardized. APTA has received substantial feedback from its members regarding administrative and technical problems with CMS payment reviews (particularly in the area of manual medical reviews for patients exceeding \$3700 of outpatient therapy services) which mirror the issues highlighted in the July 2014 released by the United States Senate Special Committee on Aging, entitled, *Improving Audits: How We Can Strengthen the Medicare Program for Future Generations* (Report).² Although the Report details audit issues, it is instructive for prior authorization procedure as well. This proposed rule states that “CMS or its contractors would conduct a medical review and communicate a decision that provisionally affirms or non-affirms the request” based on compliance with applicable coverage, coding and payment rules. As cited in federal government reports, prior problematic issues with contractor review have been extensive, vary among contractors and include:

- Boiler plate non-specific denial rationales for complex reviews
- Flawed logic semi-automated tracking systems
- Erroneous statements of “fact” in denial rationale
- Inability of provider to access clinical reviewer or management
- Ineffective problem resolution through customer service
- Apparent lack of the appropriate clinical expertise in clinical reviewers
- No contact information on website

² <http://www.aging.senate.gov/imo/media/doc/Improving%20Audits%20-%20Improper%20Payments%20Report%20-%20FINAL.pdf> (accessed July 22, 2014)

Additionally, the contractors have inadequate systems in place to accept and track documentation submitted by providers. APTA is concerned that similar issues could occur with this proposed prior authorization process if contractor's do not have the infrastructure in place or personnel with the appropriate expertise available to review these submittals in a timely fashion to comply with the 10 day (or 2 day) decision time frame.

Specifically, with regard to manual medical reviews and for outpatient therapy services exceeding \$3700, physical therapists experienced major delays in responses from Medicare contractors, despite the requirement that the review of medical necessity be completed in 10 calendar days. In a GAO report, titled "Medicare Outpatient Therapy: Implementation of the Manual Medical Review Process in 2012," (<http://www.gao.gov/assets/660/655806.pdf>), GAO identifies some of the challenges with processing approval requests that occurred. This included inability to fully automate systems for the review process to receive and track them in the allotted time frame. Overall, the MACs estimated that they completed manual medical reviews (MMRs) for about 52 percent of the total preapproval requests received within the 10 days. When Medicare patients exceed \$3700 in outpatient therapy services, providers and their patients reported major delays in the manual medical review process, overly burdensome additional documentation requests (ADRs), insufficient rationale for denials, and backlogs in the appeals process.

An additional problem was the lack of available remedies to timely correct the issues encountered. The result was excessive administrative and financial burdens on the contractors, the providers and, most importantly, treatment delays for the patient. These delays can jeopardize both the health and safety of the patient, particularly if it involves delayed receipt of the appropriate DMEPOS. **Accordingly, APTA recommends that a small set of items are tested to determine whether the proposed protocols can be operationalized on the front lines of care delivery before the program is launched nationally.** The proposed rule states that future items will be selected based on Comprehensive Error Rate Testing (CERT) data to identify items that have the highest improper payment rates. We would encourage the use of data mining and predictive analytics to target specific areas or providers that are inappropriately utilizing DMEPOS.

Additionally, CMS' implementation of a robust tracking system for tracking prior authorization affirmations/non-affirmations, prior authorization resubmittals and DMEPOS claims management is essential. Failure to have these mechanisms in place before a national plan is introduced could cause substantial delays well beyond a 10 day time frame and jeopardize patient safety and health.

We note that CMS or its contractors" will use "reasonable efforts" to communicate decisions within 10 days of receipt of a request. Even in cases not deemed an urgent condition that warrants a 2 **business** day decision, a wait beyond 10 (or 20 days) could result in serious decline of a beneficiary's health and safety. We note that private insurers generally determine prior authorizations within a 24 hour period and we encourage CMS to explore implementing private insurer processes to enable expedited determinations.

APTA is also concerned that the 2 **business** day response in cases where a beneficiary's life or health may be seriously jeopardized is problematic. DMEPOS items are needed upon hospital discharges. If a prior authorization request with the appropriate documentation is received by CMS or its contractors on a Thursday or Friday, a decision is delayed by at least 2 additional days. This additional delay could result in harm to the patient or increase costs to the facility if determined that the patient cannot be safely discharged to the home or community-based setting until the appropriate device or equipment is provided. For example, if an individual is unable to receive the appropriate wound care devices or supplies quickly – such as a negative wound therapy device - their condition could deteriorate. For example, a post-surgical wound could become infected inhibiting incisional healing or causing wound dehiscence and additional health services would be required, possibly re-hospitalization.

Additional issues regarding delays in receipt of prior authorization which can complicate a patient's medical condition include the trend that inpatient rehabilitation (IRF stays) continue to be shortened. Patients are leaving the facility sicker and are not being discharged to their final destination. The delay in receiving the appropriate equipment (e.g., air mattress, hospital bed, K0004 manual wheelchair) may delay the IRF discharge because the lack of or providing ill-fitting equipment may compromise the safety of the patient. The IRF interdisciplinary team may have to choose between discharging the patient without all their medically necessary equipment (or with off-the-shelf equipment with an improper fit) versus prolonging the IRF length of stay in order to obtain the required prior authorization. Further, a 10 day prior authorization is insufficient for a patient with a 10-14 day (or shorter) length of stay. If IRF days are counted as calendar days (vs. business days), then prior authorization days should be counted the same way.

These additional complications have long term ramifications, including increased costs and burdens on the individual, the family and the health care system, loss of a beneficiary's earning capacity if still in the work force and a reduction of quality of life.

APTA also seeks clarification on the "technical requirements" that could result in a claim denial that originally received a prior authorization affirmation. We understand the CMS example that a duplicate claim would be a valid denial that can only be determined after a claim has been submitted for processing. However, APTA recommends that prior authorizations affirming the "medical necessity" of DME items be exempt from being overturned at the claims submittal stage except in cases where defined technical issues arise (duplicate claims) or evidence of fraud or abuse becomes apparent. When a determination of medical necessity has already been made through the prior authorization process, it is unnecessary and overly burdensome on both suppliers, patients, and CMS contractors to subject the DME to a duplicative review of medical necessity.

Physical Therapist's Role - DMEPOS

A physical therapist must assess patient goals, preexisting conditions, and co-morbidities in order to provide patients with a valid, nonsurgical option that can restore and improve motion. APTA supports the practitioner's ability to deliver individualized patient care that is medically necessary to optimize health outcomes.

Physical therapists are often involved in fitting patients with orthotics, prosthetics, or the appropriate wheelchair or other medical devices during therapy treatment to facilitate function. These services - which include determining the appropriate durable medical equipment, prosthetics and orthotics supplies (DMEPOS) for the patient - are crucial to improving a beneficiaries' ability to function, participate in daily living, maintain productivity and improve the quality of their health outcomes. These services and supplies are particularly important for the Medicare population, who often are dealing with multiple health issues and co-morbidities that impact their quality of life. Timely access to the appropriate and medically necessary durable medical equipment and prosthetics and orthotic devices is important for these individuals' safety and for minimizing deterioration of their condition. The appropriate DMEPOS allow beneficiaries to safely and productively continue their activities of daily living and optimize their quality of life.

Physical therapists are involved with DMEPOS on a number of fronts, including but not limited to, in the inpatient setting to address function and mobility assessment for assistive devices, in the outpatient setting for the assessment of appropriate wheelchair or power mobility devices and in the home care setting, as prescribed by the physician, for items such as negative pressure wound therapy devices.

Wheelchairs and Power Mobility Devices

Although CMS proposes that power mobility devices involved in the CMS prior authorization demonstration would not currently be subject to this proposed rule, they could be in the future and therefore, we offer the following comments. The physical therapist's power mobility device (PMD) assessment often includes identifying seating and mobility problems, assessing the patient's potential, setting goals, and determining the necessary equipment and accessories required to achieve these goals.

Many physicians refer their patients to physical therapists who specialize in seating and mobility to insure the best outcome for the patient and to preserve Medicare funds. This process requires not only a physician face-to-face visit, but extensive assessment and documentation to support a claim for a power mobility device.

In addition to the physician face-to-face visit, documentation such as the beneficiary's medical history leading to the need for a PMD, the mobility deficits to be corrected by

the PMD, whether the beneficiary's environment can support the use of a PMD, and whether the beneficiary, or beneficiary's caregiver, is capable of operating the PMD is required. The complex interplay of these variables must also be determined and is best accomplished by an experienced clinician.

Physical therapists who conduct seating and mobility assessments consider many factors and use their clinical decision-making skills to assess the total impact of these factors in order to develop the best plan for the patient. A physical therapist who is assessing a beneficiary for a PMD will gather the following information for the history portion of the assessment: referral information (where did the referral for PMD come from), demographic data (patient's height and weight, date of birth, payer information), evaluation of typical daily mobility needs (mobility needs arising on a daily basis, patient's living environment, transportation methods, and caregiver availability), medical and surgical history, equipment use history, and functional mobility needs and goals. After this information is gathered, a physical therapist will then conduct the physical assessment of the patient. Assessment may include, but are not limited to, sitting and standing balance, upper and lower extremity range of motion, strength, trunk and pelvic posture, motor planning, pressure mapping (determining areas that may be prone to integumentary compromise), motor control and muscular endurance.

Depending on the complexity of the patient and their unique clinical picture, additional elements of the physical assessment could include trunk and neck range of motion and strength, skin integrity, sensory testing, and righting and equilibrium reactions.

A comprehensive service delivery program includes several additional elements in determining the best PMD for a patient, since the PMD will be responsible for bridging the gap between the patient's current functional status and their functional needs. These additional elements include feature and product matching, delivery and fitting, training, and goal setting. Physical therapists specializing in the areas of seating and mobility are instrumental to this process.

APTA recognizes that there can be significant benefits to prior authorization of certain DMEPOS items as long as the program is properly designed and implemented to ensure that medically necessary items are approved in proper time frames. With prior authorization, suppliers and beneficiaries will know before an item is delivered to a beneficiary whether Medicare will pay for the PMB. It can be helpful in ensuring that Medicare pays only for PMDs and other items that meet the longstanding coverage requirements, thereby limiting fraud, waste, and abuse. However, we again emphasize that should prior authorization for PMDs and other DMEPOS items be required, that the expansion occur conservatively - rather than globally - to insure that qualified individuals are reviewing and making the prior authorization determinations and that the specified time frames for review can be

met so that the program does not adversely impact beneficiaries, physical therapists, physicians, and suppliers. -

As CMS considers its policies regarding prior authorization, it is important to recognize that it is common for a patient to receive DMEPOS (e.g. wheelchair) temporarily upon discharge from a hospital or other setting and subsequently require a different DMEPOS item (e.g. wheelchair) based on a change in the patient's condition. Therefore, APTA urges CMS to establish policies that will allow coverage for temporary wheelchairs or mobility devices in the interim to enable physical therapists, physicians, and other health care professionals additional time to evaluate the patient's condition and make the appropriate recommendations regarding a permanent wheelchair based on medical necessity.

The case scenarios that follow illustrate situations in which there is a need for a temporary wheelchair prior to a permanent equipment determination:

- *Spinal Cord Injury patient:* A 68 year old male with spinal stenosis, lumbar disc disease, radiculopathy to spine is admitted to an inpatient rehabilitation facility (IRF) post-operatively. He is slowly recovering from surgery, has concomitant medical issues, is weak, but slowly improving. Because the patient's estimated IRF length of stay is up to 9 days (based on the plan of care), the patient and interdisciplinary team would not be able to anticipate the patient's definitive long term equipment needs in that time frame. The patient's condition is not stable – it could improve or decline or plateau – so the equipment that the patient leaves with upon IRF discharge may not be appropriate for the long term use (or the life time of the equipment). One scenario is that the patient needs a power wheelchair to go home because he is weak, unable to perform a weight shift or propel sufficiently to be home alone without a power wheelchair. As he continues with outpatient physical therapy or home physical therapy, he improves to the point where he can use a manual wheel chair, and/or other assistive devices.

In another scenario, the patient may discharge home in a high strength lightweight wheelchair. He finds that he is unable to efficiently propel his wheelchair to get to the bathroom, and/or the time and effort it takes to complete all his home mobility and mobility-related activities of daily living (MRADLs) are too costly from an energy conservation standpoint due to co-morbidities (Congestive heart failure (CHF), cardiac issues, Chronic Obstructive Pulmonary Disease (COPD), Oxygen desaturation, pain, dialysis, renal vascular disease, etc.).

- ***Amputee or stroke patient:*** An amputee patient leaves the inpatient hospital, after a 4 day length of stay and whether this patient will be functionally ambulatory is unclear at that time. Further, the patient has co-morbidities, which initially caused the non-traumatic amputation. The patient may need both a prosthesis and a wheelchair. The patient may require additional time to rehabilitate at home or in an outpatient setting in order to determine whether the patient will be able to safely and functionally ambulate with a prosthesis or will require a wheelchair. Whether the patient will be functionally ambulatory has not yet been determined or whether s/he will be able to propel a manual wheel chair or require a power wheel chair remains to be seen.
- ***Large patient with a medical condition in need of a wheelchair:*** A patient is unable to propel a K0004 wheelchair. He is 6'2" tall and is unable to fit in a K0004 wheelchair because of the limited size configurations. He needs a K0005 wheelchair to safely go home, but needs to go through the outpatient physical therapy process in order to determine what his/her definitive equipment needs are, which could be power, K0005, or K0005 and power assist wheels.

These examples clearly demonstrate the need to have the proper mechanisms in place so that the DMEPOS prior authorization requests for affirmation in these situations are not denied.

Conclusion

APTA recognizes that oversight of DMEPOS utilization is necessary; however, it is of limited value if delays cause detrimental health impacts on beneficiaries or impose additional administrative and financial burdens on providers and suppliers due to operational and technical issues. The prior authorization process should neither delay the provision of care, nor be overly burdensome to providers or patients. It is vitally important that individuals, especially vulnerable populations such as the aged and the disabled populations, are able to access DMEPOS that are medically necessary for their health condition. The inability to obtain the appropriate equipment or devices results in a substantial cost to beneficiaries, the Medicare program and the health care delivery system as a whole.

APTA commends CMS on allowing stakeholders the opportunity to comment on this important regulation which could reduce DMEPOS overutilization on select items if efficiently operationalized. APTA looks forward to working with CMS in its efforts to ensure that Medicare beneficiaries timely receive the appropriate medically necessary DMEPOS. Thank you for your consideration of our comments. If you have any questions, please contact Deborah Crandall, J.D., Senior Regulatory Affairs Specialist, at 703-706-3177 or deborahcrandall@apta.org.

Sincerely,

Paul Rockar Jr.

Paul Rockar, Jr. PT, DPT, MS
President

PR/dc

