Experts' Roundtable

In a recent letter to CMS Administrator, Dr. Mark McClellan, Stephen McConnell, Vice President of Advocacy and Public Policy at the Alzheimer's Association, detailed the difficulties that some beneficiaries have had in accessing their Alzheimer's drugs, specifically regarding the use of prior authorization for the 4 available Alzheimer's drugs: Aricept® (donepezil HCl), Excelon® (rivastigmine tartrate), Razadyne® (galantamine HBr), and Namenda® (memantine HCl). The letter appears on page 41.

In this issue, we asked our panel of experts to comment on the problem.

Editor's Note: See Roudtable Update on page 43.

You are invited to make suggestions for Roundtable discussions in future issues of ALC.

Some Medicare providers are reporting difficulty accessing Alzheimer's drugs from some Medicare prescription drug plans (PDPs). Some plans require prior authorization for all FDA-approved Alzheimer's medications. We asked the experts to comment on how physicians and others should respond to this problem.

Scott Matthew Bolhack, MD, CMD, FACP, FAAP
CEO, TLC HealthCare™ Companies
Tucson, AZ

The access of medications under the Medicare Part D plan has incurred another obstruction: the necessity of prior authorization for medications for Alzheimer's disease in certain nationally based. While on the surface, Dr. McClellan's observations appear relevant, it is a predictable maneuver by CMS to transfer the risk of the cost of medical care down to the vendor or provider level. The consumer had the opportunity to choose their own Medicare pharmacy benefit, and these prior authorization issues needed to be addressed by the consumer before the end of March, 2006 enrollment period. Of course, as we all know, this process was confusing enough without being expected to comprehend the nuances of prior authorizations, let alone the myriad of other pharmacy issues. The inappropriate use of these medications justifies these plans to initiate a process in which providers need to prove why these medications are needed for their patient.

Dr. McClellan believes that the thousands of providers who order these medications all understand exactly why the medications are needed, how they should be used, have explained the side effects to their patients, have concrete criteria to terminate the medications, and even that they understand the off-label uses of these medications. There is enough damning medical inconsistencies perfectly outlined in his letter to encourage almost any Medicare Part D plan to initiate their own prior authorization process effective retroactively to April 1, 2006.

For those of us who have practiced in heavily managed care senior markets, the prior authorization process has been part of our practice patterns for more than a decade. Remember, providers are obligated to recommend a treatment, even if the insurance plan does not agree with it [by refusing to authorize (pay for) the treatment]. From a scientific standpoint, physicians need to solidify how these medications should really be used. Thousands of physicians with thousands of independent ideas of how these medications should be utilized are not reasonable from any perspective. The "policy" of prior authorizations is no worse than the inappropriate utilization of medications by providers.

From a process point-of-view, a centralized clearing house for prior authorizations with a single form and process would be the best long-term solution. Ideally, this could be handled online through computer technology.

Anne Ellett, MSN, NP-C
Vice President, Health Services
Silverado Senior Living
San Juan Capistrano, CA

The letter from Stephen McConnell dated June 12, 2006, of the Alzheimer's Association to Dr. Mark McClellan highlights some compelling issues for today's health care system in regard to the standard of treatment for those millions of Americans affected by Alzheimer's disease. Today in the United States, Alzheimer's disease affects over 4 million people. National demographics indicate that the percent of our census who are elderly and have Alzheimer's disease will rapidly increase in the next few years.

Medicare beneficiaries who are over 65 years old are those who are most commonly affected by Alzheimer's disease and other memory-impairing conditions. There are now FDA-approved medications for treatment of this condition. Research has shown that for many Alzheimer's patients, their decline is slowed with proper treatment, allowing for longer independence and less need for caregiver supervision.

Prior approval for these medications is a logistic barrier that many elderly caregivers are unable to navigate to access proper treatment. In addition, the requirement of frequent testing, such as the Mini-Mental State Examination (MMSE), is another artificial barrier that does not provide any real information to CMS about the Alzheimer's patient's condition. The examining physician or other qualified health care providers

are in the best position to determine whether a patient might benefit from a trial of an FDA-approved treatment. Barriers from health care plans, such as Medco, RxAmerica, and Caremark, need to be removed to improve access to these treatments. Physicians and other health care professionals should continue to advocate for Alzheimer's patients and their families to have all barriers removed from accessing these FDA-approved treatments.

Brian Smith
President
Assisted Living Pharmacy Association
Fort Lauderdale, FL

Brian Smith commented on how difficult an issue this has become by explaining that it plagues pharmacy providers, as well as physicians. He stated, "It requires much extra work on the part of all providers, and often ends up with negative outcomes. Since pharmacy providers have little to no leverage with PDPs (mostly none), they have to manage to the their best abilities with what they have." He advised pharmacies, families, and residents to pick their plans carefully. AL residents should consult their pharmacy provider concerning their drugs and the plans available prior to choosing a PDP since some plans, such as Community Care RX, are more flexible when it comes to formulary selection and approval processes. He remarked that it is much harder, in fact nearly impossible, for pharmacies to control the selection process for AL residents. According to Smith, "The bottom line is that providers, families, and residents really need to seek the advice of an appropriate pharmacy provider or consultant about how to obtain optimal access to their drugs."

Richard Stefanacci,
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Accessing appropriate medications for our Medicare beneficiaries through PDPs has certainly been an issue. No one should be surprised by this. After all, PDPs are financially responsible only for the cost of medications; therefore, they have every incentive to restrict access to medications. What has come as a surprise are the aggressive and strange manners that PDPs have already taken to restrict access to the Alzheimer's medications. No one had predicted that plans would require MMSEs to justify the use or continued use of these important medications. Many providers are turning to consulting specialists, such as neurologists, to provide justification to PDPs for the use of these medications. I believe this is a costly mistake. Think about not only the burden to the health care system for these extra consults, but to our AL residents who are forced out of their homes to spend time and money on this process. In my mind, a better system is for providers to develop standard forms to send to plans, justifying the use of the medication and pointing out the danger to the PDPs for refusing coverage. Tracking MMSEs is not a bad idea and should be utilized to gauge the progression of the disease, but it should never be used as justification for the payment of these important medications. Without having systems in place so providers can deal with PDPs in an efficient and effective manner on issues such as the restrictions placed on Alzheimer's medications, AL residents are going to be forced to bear unnecessary expenses and delays in treatment. And this is certainly not what any dedicated health care provider wants since the delay in treatment of Alzheimer's disease is likely to accelerate the premature departure from an AL residence to a skilled nursing facility.

alzheimer's association®

June 12, 2006
Re: Access to Alzheimer's drugs

Dear Dr. McClellan,

On behalf of the Alzheimer's Association and its constituents, we applaud your efforts over the past two years to implement a new outpatient prescription drug benefit for Medicare beneficiaries. We appreciate the numerous opportunities to work with you and your staff to address the difficulties that are inevitable when developing a new and complex program. It is in the spirit of our collaboration that we request a meeting with you to discuss serious problems that some Medicare beneficiaries are having accessing their Alzheimer's drugs in a few Medicare prescription drug plans after March 31, 2006, the end of the initial transition period.

Over the past two months, we have received a significant number of complaints regarding the use of prior authorization for the four Alzheimer's drugs: Aricept, Exelon, Razadyne and Namenda. The vast majority of the complaints are about three national or near-national plans: Medco, RxAmerica and Silverscript (Caremark). Based on the April 27, 2006, data released by the Centers for Medicare and Medicaid Services (CMS), these plans have approximately 8% of the market share for total enrollment. Contrary to all of the other national plans, these three plans require prior authorization for all of the FDA-approved medications for Alzheimer's disease. The other national plans do not require prior

authorization for any of the Alzheimer's drugs on their formularies.

Inappropriate Use of the Mini-Mental Score Examination

The general criterion for the prior authorization review is diagnosis of Alzheimer's disease and score on the Mini-Mental Score Examination (MMSE). These plans appear to restrict access to these medications based on the individual's MMSE and the FDA labeling of the respective drugs. As you know, cholinesterase inhibitors have been approved for mild to moderate disease and memantine for moderate to severe. The precise delineations among these states are imprecise. The MMSE is a commonly used *screening* tool but is not an appropriate measure for obtaining approval for medications. It is the clinical judgment of the treating physician that should determine whether and which drug is appropriate, at what stage and for how long. The MMSE is too coarse to make this determination, especially since the categorization of an individual as to mild, moderate or severe is based on more facets than just a score on a test. The MMSE does not account for function (activities of daily living) or other measures which are equally as important in making a clinical assessment of stage of the disease progression. In addition, there are educational, cultural and other factors that influence a test score which could adversely affect lower educated or culturally diverse individuals.

"Off-Label" Use of Medications

In a March 30, 2006, meeting with representatives of beneficiary and disease organizations, you stated that it is not appropriate for Part D plans to limit the dosage and usage of medications to the FDA labeling. We concur with and support your position. It is standard clinical practice for physicians to prescribe off-label use of medications that they believe will benefit their patients. In the case of people with Alzheimer's disease, it is the current standard of care and practice for doctors to prescribe Alzheimer's drugs for patients which may fall outside the severity or duration of the FDA-approved drugs, but for which the patients continue to benefit. Since FDA-approval of the Alzheimer's drugs, there have been recent studies that indicate that there are positive effects on patients who continue the medication outside of the FDA-approved label. Pertinent studies include:

- Donepezil in patients with severe Alzheimer's disease: double-blind, parallel-group, placebo-controlled study. Bengt Winblad, Lena Kilander, Sture Eriksson, Lennart Minthon, Stellan Batsman, Anna-Lena Wetterholm, Cararina Jansson-Blixt, Anders Haglund. *Lancet.* 2006 Apr 1;367(9516):1057-65.
- Donepezil in vascular dementia: combined analysis of two large-scale clinical trials. Roman GC, Wilkinson DC, Doody RS, Black SE, Salloway SP and Schindler RJ. Dement Geriatr Cogn Disord.2005; 20(6):338-44. *Epub* 2005 Sep 23.
- A double-blind, placebo-controlled multicentre study of memantine in mild to moderate vascular dementia (MMM500). Wilcock G, Mobius HJ, Stoffler A, *Int Clin Psychopharmacol.* 2002 Nov;17(6):297-305.
- Memantine in the treatment of mild to moderate dementia syndrome. A double-blind placebo-controlled study. Gortelmeyer R, Erbler H. *Arzneimittelforschung.* 1992 Jul;42(7):904-13.

Miscellaneous Issues

In a recent complaint from a physician in Sikeston, Missouri, patients were denied the Alzheimer's drugs when he answered affirmatively to the question "Is the disease progressing?" The FDA approved these medications to treat the symptoms of Alzheimer's disease only. None of the Alzheimer's drugs cure or stop the underlying course of the disease. The denial of prior authorization due to disease progression is improper and unacceptable.

Silverscript/Caremark appears to require an MMSE every three months. As discussed above, the use of the MMSE is inappropriate. In addition, the requirement that the MMSE be administered every three months will increase Part B costs for insupportable and invalid purposes.

Conclusion

We believe that the use of prior authorization for Alzheimer's drugs is inappropriate. In addition, while some at CMS believe that the denial of prior authorization can be addressed through the exceptions and appeals process, this approach is unrealistic and unreasonable. Neither frail patients nor their physicians can be expected to navigate the plan system and file additional documentation in order to obtain to these medications that are on the plan's formulary. The unfortunate consequence will be that patients will not receive the medications from which they will benefit.

The Alzheimer's Association believes the prescribing physician is in the paramount position to determine whether the FDA-approved medications are appropriate, including those that may be considered "off-label" prescriptions. We do not believe this should be a decision by a drug plan and certainly not one that relies on a single, inappropriate score. We appreciate your attention to this matter and request your assistance in correcting what we strongly believe to be a faulty policy by a small minority of plans.

Yours truly,
Stephen McConnell
Vice President of Advocacy and Public Policy

Roundtable Update

Medco Removes Prior Authorization for Alzheimer's Drugs

In response to a June 12, 2006 Alzheimer's Association letter to the Centers for Medicare and Medicaid Services (CMS), Administrator, Dr. Mark B. McClellan (see page 41), Medco removed its prior authorization policy for Alzheimer's drugs for Medicare Part D beneficiaries over age 65. As of July 15, 2006, Medco no longer requires prior authorization for all FDA-approved drugs to treat Alzheimer's disease.

The Alzheimer's Association applauds Medco for making this important change to its formulary policy. With Medco's policy change, only 2 national plans still require prior authorization: RxAmerica and Silverscript (Caremark). However, Silverscript (Caremark) is in the process of developing a modification to its prior authorization requirements and is in discussion with CMS.

The Medco policy reversal is a significant advocacy victory. It is the Alzheimer's Association's position that the doctor-patient relationship should be at the core of medical treatment, and that only the clinical judgment of the treating physician in conjunction with the patient/family should determine the appropriateness of a drug for a patient and how long it should be used.

For more information about this topic, access the Alzheimer's Association Fact Sheet, "Important Things to Consider When Choosing a Medicare Drug Plan for People With Alzheimer's Disease," available at: www.alz.org/Resources/FactSheets/MedicareRX_PWDChooseplan.pdf. ALC

The Interdisciplinary Team
(continued from page 39)

reduce the functional decline and disability in AL residents with chronic pain. Lastly, education of individual residents, as well as staff, on safety, fall prevention, transfer techniques, joint and energy conservation, general health and wellness, and the effects of immobility is also within the scope of PT services.

PT for Residents with Cognitive Impairment

As the disease process progresses, the functional needs of a resident will change. Consequently, the role of the PT and the goals of therapy will also change to reflect the progression of the disease process. Frequent interdisciplinary communication and education of the direct caregivers are essential aspects of PT interventions for cognitively impaired residents.

Mild Cognitive Impairment
In residents with mild cognitive impairment, a PT can provide a fall prevention assessment, including a balance evaluation, and initiate an exercise program to maintain mobility, strength, balance, and gait. A PT can also teach residents with mild cognitive impairment strategies, including verbal and visual memory cues, to maintain their level of independence during functional activities.

Moderate Cognitive Impairment
As a resident's mental status progresses to a level of moderate cognitive impairment, repeated fall prevention assessments are indicated. Balance and gait training that includes the use of an assistive device, additional caregiver education, and modifications to the environment may be warranted. A PT can educate the caregiver staff on how to best assist the resident with functional activities, as well as recommend strategies to prevent and manage challenging behaviors.

Severe Cognitive Impairment
When a resident demonstrates severe cognitive impairment and can no longer ambulate safely, a PT can recommend and assist with the procurement of a custom wheelchair and seating system. A resident is often able to safely self-propel when properly fitted in a wheelchair. As the disease progresses to its end stage, a custom wheelchair can encourage proper posture, resulting in improved breathing, feeding, and socialization. Pressure relief and wound prevention are also potential benefits of a custom wheelchair and seating system.

A PT can teach residents with mild cognitive impairment strategies to maintain their level of independence.

Final Thoughts

PTs are experts in safe functional mobility and its components, including gait, balance, fall prevention/management, transfers, cardiovascular endurance, strength, flexibility, wheelchair mobility, and therapeutic exercise. The utilization of PT services by residents and interdisciplinary teams can be beneficial in maintaining safe functional independence and maximizing the quality of life for AL residents. ALC

Mimi Jacobs, PT, OCS, CSCS is a physical therapist and the Director of Research and Presentations for Fox Rehabilitation, providing rehabilitation services to multiple AL facilities in the New York, New Jersey, Pennsylvania tri-state area.