More than 2 million elderly Americans live in long-term care settings such as nursing homes. In 2011, 24% of residents in US long-term care facilities were taking antipsychotic medications. Medicare Part D paid $7.6 billion for antipsychotic medications in 2011, which was the second highest amount spent on any class of drugs. Over the past five years, several pharmaceutical companies have inappropriately marketed their antipsychotic medications for use in older adults with dementia, in one case resulting in more than $2.2 billion in fines—the third-largest pharmaceutical settlement in US history.

Prescription medications that target psychological and behavioral symptoms of dementia have been overused in long-term care facilities and are associated with adverse events and increased rates of death.

In response, the Centers for Medicare and Medicaid Services (CMS) has required dose reduction and discontinuation of these medications in long-term care facilities.

It is essential to end the overuse and misuse of these medications, but also important to recognize that their benefits may outweigh the risks in some patients.

Medication reduction and discontinuation may not be appropriate goals for all patients, and such decisions should be made by physicians involved in the patient’s care, not by regulators.

In addressing the overuse and misuse of medications that target the psychological and behavioral symptoms of dementia, it is important not to let the pendulum swing too far by making the medications unavailable for patients who may benefit.
Antipsychotic medications in patients with dementia can cause adverse side effects, such as increased risk of stroke, falls, sedation, metabolic changes, and movement problems. Moreover, these medications have been linked to an increased risk of death in patients with dementia. In 2007, 88% of claims for a sub-group of antipsychotic medications known as the atypicals for elderly nursing home residents were actually for patients with dementia, although the FDA specifically warns that these medications are associated with an increased risk of death in this population.

**Definitions**

- **Psychotropic medications:** medications that affect mental processes and behavior such as antipsychotics for psychosis, antidepressants for depression, and anxiolytics for anxiety
- **Antipsychotic medication:** a medication used to treat psychosis
- **Atypical antipsychotic medication:** a second-generation medication used to treat psychosis that has fewer motor side effects than typical antipsychotic medications
- **Psychosis:** a condition characterized by a psychological break from reality, often involving hallucinations (seeing or hearing things that others don’t) and/or delusions (false beliefs that are often bizarre or paranoid)
- **Dementia:** a condition of memory loss and other deficits in thinking and behavior that can accompany brain diseases such as Alzheimer’s and Parkinson’s

Clearly, the overuse and misuse of psychotropic medications in patients with dementia must stop. In an attempt to address these problems, CMS has called for a rigorous review of psychotropic medication use in residents of long-term care facilities. CMS’ proposed rule, *Reform of Requirements for Long-Term Care Facilities*, states that residents should receive gradual dose reduction of all psychotropic medications in an effort to discontinue them.

Regulators must be mindful, however, that patients with brain diseases such as Alzheimer’s and Parkinson’s frequently face psychological symptoms that can be difficult to treat. The recommended first-line treatments for these symptoms, behavioral and cognitive therapies, are not effective for all patients. Although research may lead to safer and more effective alternatives in the future, in the meantime, existing medications for psychosis and other psychological symptoms must not be taken off the table altogether.
CMS’ PROPOSED RULE ASSUMES A ONE-SIZE-FITS-ALL APPROACH

Not all patients in long-term care are the same: in some, the benefits of psychotropic medications may outweigh the risks, whereas in others they may not. Consequently, discontinuation of these medications may be appropriate for some patients but detrimental to others. For example, discontinuing antipsychotic medications may not be recommended in dementia patients with severe psychological symptoms.

REGULATIONS SHOULD NOT SUPERSEDE MEDICAL JUDGMENT

CMS’ proposed rule regarding psychotropic medications must not supplant physician judgment. If a patient is diagnosed with a condition for which the medication is approved, the physician then weighs the potential benefits versus the risks based on his or her knowledge of the patient, taking into account co-existing medical conditions and other medications—personalizing care in a way that insurers cannot. Thus, policymakers and CMS should consider an exception from dose reduction requirements when the medication is approved by the FDA for the condition it is being used to treat.

Physician judgment is also critical for patients with conditions for which no medications are approved. In such cases, physicians should be able to prescribe psychotropic medications where professional, evidence-based guidelines exist. Ultimately, decisions as to which treatment a patient in long-term care receives should be made by physicians in collaboration with other clinicians, family, and caregivers involved in the patient’s care.

ALZHEIMER’S DISEASE

- 90% experience behavioral and psychological symptoms
- 41% experience psychosis
- 36% experience delusions
- 18% experience hallucinations
- 21% experience apathy
- Psychosis is associated with greater cognitive impairment and faster rate of cognitive decline.

PARKINSON’S DISEASE

- 80% experience dementia at some point during their illness
- 66% experience depression
- 65% experience anxiety
- ≥ 60% experience psychosis at some point during their illness
- Dementia is associated with higher rate of psychological symptoms.

Ultimately, decisions as to which treatment a patient in long-term care receives should be made by physicians in collaboration with other clinicians, family, and caregivers involved in the patient’s care.
It is important to preserve these medications as options for carefully selected patients in long-term care without stigmatizing them.

**Negative Attitudes Toward Psychotropic Medications Could Undermine Patient Access**

A less tangible issue with CMS’ proposed rule is the negative portrayal of psychotropic medications. They are described as treatments to be discontinued, without recognizing any potential benefits. Psychological symptoms associated with brain diseases are distressing for patients and their family and caregivers, and may significantly reduce quality of life.15,16 Psychotropic medications can sometimes help patients and families obtain relief. It is important to preserve these medications as options for carefully selected patients in long-term care without stigmatizing them. Negative attitudes could undermine adoption of new psychotropic medications that become available, which may not be in patients’ best interest.

**Conclusions**

Patients with brain diseases in long-term care deserve the best treatments available as they struggle daily with mentally distressing symptoms. For many patients, behavioral and cognitive therapies can help minimize these symptoms, but, when these treatments are inadequate, psychotropic medications may provide relief in carefully selected patients. This decision should be made by physicians involved in the patient’s care and should not be countermanded by regulations that do not take into account individual patient needs. In addressing the overuse and misuse of psychotropic medications in long-term care settings, it is critical to avoid letting the pendulum swing too far. These medications can and do help some patients, whose needs must not be forgotten in the quest to formulate policy designed to protect a population of patients from harm.
REFERENCES


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