

## National Initiative Examines Antipsychotic Drug Use in the Elderly

In 2012, the Centers for Medicare and Medicaid Services (CMS) developed the CMS National Partnership to Improve Dementia Care in Nursing Homes. One of the goals set by this program was to achieve a 15 percent reduction in antipsychotic drug use within nursing homes. The creation of this goal was due in part to the U.S. Department of Health and Human Services Office of Inspector General (OIG) report released in 2011, which indicated that in nursing homes:

- Eighty-eight percent of atypical antipsychotic drug claims were for patients with dementia, an indication with a black box warning.
- Eighty-three percent of atypical antipsychotic drug claims were for non-U.S. Food and Drug Administration (FDA) labeled indications (off-label indications).
- More than 50 percent of atypical antipsychotic drug claims were improperly billed to Medicare due to the fact that Medicare does not cover off-label indications which are not supported by drug compendia.
- Twenty-two percent of atypical antipsychotic drugs claims were not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes due to excessive dose, duration, inadequate monitoring or continuation despite adverse effects.<sup>1</sup>

A separate OIG report released in 2012 indicated that long term care facilities were not in compliance with federal requirements for the documentation of patient assessments, decision making, care plan development and care plan implementation in patients receiving antipsychotics.<sup>2</sup>

### Risks of Antipsychotic Drug Use in the Elderly

**The FDA Black Box Warning** for both conventional and atypical antipsychotics outlines the increased risk of mortality in elderly patients **treated for dementia-related psychosis**. The FDA warning is based on a review of 17 placebo-controlled trials studying 5,377 elderly patients with dementia-related behavioral disorders. The studies reported a 1.6 to 1.7 times greater increase in death with the use of atypical antipsychotics compared with the placebo group. Additionally, two large epidemiologic studies with a combined population of 37,241 elderly patients found that the increased risk of death was similar between conventional and atypical antipsychotics.<sup>3</sup>

In addition to risks for increased mortality, antipsychotic drug use in the elderly is associated with an elevated risk of cerebrovascular events, adverse metabolic effects, extrapyramidal symptoms, falls, cognitive worsening, cardiac arrhythmia and pneumonia. Conventional antipsychotics may pose an even greater safety risk.<sup>4,5</sup>

### Gradual Dose Reductions

Gradual dose reductions are an important tool in minimizing adverse effects of antipsychotic medications. Tapering of antipsychotics allows medical providers to determine the medication's true efficacy, the need to continue the medication and optimal dosing. In nursing homes, gradual dose reductions should be conducted annually unless clinically contraindicated.<sup>4,5</sup>

### Prescribing of Antipsychotic Drugs to the Elderly

According to CMS<sup>4</sup>, antipsychotics prescribed for the elderly in nursing homes should generally be used only in the treatment of the following conditions as identified by the Diagnostic and Statistical Manual of Mental Disorders:

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| <ul style="list-style-type: none"> <li>• Delusional disorder</li> <li>• Hiccups (not induced by other medications)</li> <li>• Huntington disease</li> <li>• Mood disorders (e.g., bipolar disorder)</li> <li>• Medical illnesses with psychotic symptoms (e.g., neoplastic disease or delirium)</li> <li>• Nausea and vomiting associated with cancer or chemotherapy</li> </ul> | <ul style="list-style-type: none"> <li>• Psychosis (in the absence of dementia)</li> <li>• Schizo-affective disorder</li> <li>• Schizophrenia</li> <li>• Schizophreniform disorder</li> <li>• Treatment related psychosis or mania (e.g., high-dose steroids)</li> <li>• Tourette's Disorder</li> </ul> |
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Antipsychotics may occasionally be considered for behavioral or psychological symptoms of dementia (BPSD) if:

- The behavioral symptoms present a danger to the patient or others;
- AND one or both of the following criteria are present:
  - The symptoms are identified as being due to mania or psychosis (such as: auditory, visual, or other hallucinations; delusions, paranoia or grandiosity); OR
  - Behavioral interventions have been attempted and included in the plan of care, except in an emergency.<sup>4,5</sup>

### Summary

Neuropsychiatric symptoms such as agitation and delusions occur commonly in elderly patients with dementia and often cause significant distress. Data on treatment efficacy are strongest for atypical antipsychotics, but these agents must be used with great caution. An antipsychotic drug trial is warranted when non-pharmacological intervention is unsuccessful and neuropsychiatric symptoms or associated behaviors cause severe distress or pose a significant safety risk. Risks, benefits and alternatives should be discussed with the patient and, if applicable, the surrogate decision maker, with an opportunity given to ask questions. Dosages should be the lowest necessary and metabolic parameters should be regularly monitored. Face-to-face visits are important to monitor response, tolerance and the need for continued treatment. For patients in whom neuropsychiatric symptoms have been much improved or have been in remission for 3-6 months, a discontinuation trial should be considered. Through careful selection of appropriate patients for treatment, education of patients and caregivers and close monitoring, safety risks can be minimized.

### References

1. Department of Health and Human Services-Office of the Inspector General. Medicare Atypical Antipsychotic Drug Claims to Elderly Nursing Home Residents. May 2011. OEI-07-08-00150. <https://oig.hhs.gov/oei/reports/oei-07-08-00150.asp>
2. Department of Health and Human Services-Office of the Inspector General. Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs. July 2012. OEI-07-08-00151. <https://oig.hhs.gov/oei/reports/oei-07-08-00151.asp>
3. U.S. Food and Drug Administration. Information for Healthcare Professionals: Conventional Antipsychotics. August, 15, 2013. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm>
4. Department of Health and Human Services. Advanced Copy: Dementia Care in Nursing Homes: Clarification to Appendix P State Operations Manual (SOM) and Appendix PP in the SOM for F309 – Quality of Care and F329 – Unnecessary Drugs.
5. Department of Health and Human Services. CMS Manual System Pub. 100-07 State Operations Provider Certification. <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r22soma.pdf>

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