

Medicare Part D News Update Utilization of Antipsychotics in the Elderly Population

Background: In the elderly population antipsychotics are typically used to treat three conditions:

1. Psychotic disorders like schizophrenia.
2. Psychotic symptoms (delusions, hallucinations, etc.) associated with another condition like Alzheimer's or delirium.
3. Treatment of behavioral and psychological symptoms associated with dementia (BPSD) when there is **potential for harm to the individual or others**.

Many elderly individuals experience BPSD, but pose no harm to themselves or others. Therefore, the use of antipsychotic medications in these patients should be considered only in very limited circumstances as their use may actually result in more harm than benefit. Current BPSD treatment guidelines may be utilized to assist the provider in the appropriate treatment of the underlying cause of the patient's behavior and psychological symptoms.

Atypical antipsychotics (e.g. Risperdal, Zyprexa, Seroquel, etc.) carry an FDA Black Box Warning for increased risk of death when used in the elderly. As a result, providers should consider if anticipated benefits would outweigh the increased risk that this class of agents represents to this at-risk patient population.

The Office of Inspector General (HHS - OIG) has published two reports regarding the use of antipsychotic medications in the elderly. Both reports have outlined significant level of inappropriate antipsychotic use. As a result, their recommendations are focused on preventing unnecessary harm to patients.

The first OIG report documented that nearly all nursing facilities were noncompliant with basic requirements for administration of antipsychotic medications. There are four steps required by CMS to properly complete the resident and care plan process. One third of the medical records reviewed did not contain the appropriate documentation of compliance with Federal requirements regarding resident assessment. In addition, 18% of records did not contain any documentation about the planned intervention involving antipsychotic use. Due to the safety concerns surrounding these drugs, the OIG and CMS agree that there is a need for improvement within LTC facilities regarding these basic requirements. The OIG and CMS also recommend that measures are taken to address noncompliance with these issues. These recommendations include enhancement of patient assessments and care plans for the elderly on antipsychotics.¹ Evaluation and assessment of appropriateness of antipsychotic therapy should be performed regularly. When treating the elderly with antipsychotics, the plan of care should be clear at all times, due to the risk of adverse events and death.

The second OIG report focused on the costs surrounding antipsychotic use in the elderly. A significant concern of the investigators was the potential for off-label use. Of particular concern was the use of antipsychotics in situations as detailed in the FDA Black Box Warning (e.g. use of antipsychotics in elderly patients with dementia-related psychoses, etc.). The four key findings from this OIG report are²

1. Fourteen percent of elderly nursing home residents had Medicare claims for atypical antipsychotics.
2. Eighty three percent of the claims were associated with off-label conditions and 88% were for conditions that were mentioned in the Black Box Warning.
3. Fifty one percent of Medicare atypical claims for elderly nursing home residents were "erroneous" (usually because it was off label); amounting to \$116 million dollars.
4. Twenty two percent of these atypical antipsychotic drugs claims were not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes.

Additional Medical Literature review:

In another study, a cohort from Medicare and Medicaid claims evaluated the use of antipsychotic use in a population of 75,445 elderly patients from 2001 to 2005. Comparisons were made against a reference group of patients taking risperidone. Patient groups were controlled for potential confounders. Interestingly, patients taking haloperidol had double the risk of mortality while other antipsychotic agents had varying but lower risk for all cause mortality.³

Lastly, in 2005 the FDA issued a public health advisory in response to a study of 15 placebo-controlled trials in which death occurred in 3.5% of elderly patients treated with atypical antipsychotics while death occurred in 2.3% of patients randomized to placebo. The important take-away message from this advisory was that anti-psychotics, both typical and atypical agents, pose a significant risk to elderly patients with dementia.⁴

Summary:

1. Antipsychotic medications cause an increase in risk of death in the elderly population.
2. The FDA has placed a Black Box warning on antipsychotics cautioning against use in the elderly and risk of death.
3. Antipsychotics are not recommended for the treatment of BPSD in the elderly with dementia; non-pharmacologic methods should be exhausted first.
4. Despite carrying a Black Box warning, antipsychotic use in the elderly patient population (with dementia) is still commonly found in clinical practice.
5. The OIG and CMS have recommended enhanced evaluation and assessment of the elderly on antipsychotics to appropriately manage therapy. A care plan is also needed to assure appropriateness of therapy and weigh the risk of adverse effects of these agents.

References:

1. 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>
2. 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>
3. Huybrechts KF, Gerhard T, Crystal S, Olfson M, Avorn J, Levin R, Lucas JA, Schneeweiss S. [Differential risk of death in older residents in nursing homes prescribed specific antipsychotic drugs: population based cohort study](#). BMJ. 2012 Feb 23; 344:e977.
4. Maher AR, Theodore G. [Summary of the comparative effectiveness review on off-label use of atypical antipsychotics](#). J Manag Care Pharm. 2012 Jun; 18(5 Suppl B):S1-20.