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POLICY

Use of Antipsychotic Medications in Nursing Facility Residents

Preamble

The Office of Inspector General of the U. S. Department of Health and Human Services issued a report in May 2011 finding that 14% of elderly nursing home residents had Medicare claims for atypical antipsychotic drugs.[1] In addition, 83% of the above Medicare claims for atypical antipsychotics for these elderly nursing home residents were for off-label indications.

In 2005, the U. S. Food and Drug Administration required manufacturers of atypical antipsychotic medications to include a boxed warning that these antipsychotics may increase the risk of death in elderly persons with psychosis related to dementia. This warning was expanded to all antipsychotic drugs in 2008. The OIG report found that 88% of the use of atypical antipsychotics was in persons for whom this warning is applicable.

As part of the report, OIG conducted medical record reviews on 600 elderly nursing facility residents. They found that 22% of the atypical antipsychotic medications were not administered in accordance with standards from the Centers for Medicare & Medicaid Services relating to unnecessary drug use in nursing homes.

This controversial report from the OIG has generated concern about the use of antipsychotics in patients with dementia, and also criticism of the report itself.[2-4] This document will provide additional background on this subject and a position statement from the American Society of Consultant Pharmacists.

Background

Understanding the findings and implications of the OIG report on use of atypical antipsychotics in nursing home residents requires placing the report findings into a proper context. Shown below are key points to understanding this report.

1. *The prescribing of a medication for an off-label indication is a common practice and does not necessarily reflect inappropriate prescribing.*

Radley and colleagues studied the off-label prescribing of medications by office-based physicians and found that 21% of all medication prescribing was for off-label indications.[5] This rose to 31% for psychiatric medications and 46% for cardiac medications.

Approval of an indication for use by the FDA requires a formal request from the manufacturer of the medication, along with supporting evidence. Obtaining this approval can be very expensive for the manufacturer. Once a drug's patent has expired, or is nearing expiration, the manufacturer has no economic incentive to have these new indications evaluated by the FDA, even if there is strong scientific support in the medical literature.

Elderly persons with dementia frequently present with behavioral or psychological symptoms that occur in conjunction with this illness. These symptoms are collectively referred to as BPSD (Behavioral and Psychological Symptoms of Dementia). In Canada, risperidone (an atypical antipsychotic) has been approved for this indication.[6] In the United States, no medication has been approved by the FDA for this indication. Therefore, any medication prescribed to treat BPSD in the US would be considered off label.

2. *The prescribing of a medication in the presence of a "black box" warning in the FDA labeling is not necessarily inappropriate.*

The decision to prescribe a medication for a patient requires consideration of the expected benefits of the medication and the potential risks. The role of the prescriber, in conjunction with the patient and/or caregiver, is to determine whether the benefits of the medication outweigh the risks. Information contained in a black box warning should be considered as part of the prescribing decision. Nevertheless, it may be appropriate in some cases to use the medication despite the potential risks if the benefits are considered sufficient to outweigh these risks.

In the case of an elderly nursing home resident with dementia, the presence of distressing hallucinations or paranoid delusions can greatly diminish quality of life for the individual. In addition, certain behavioral symptoms can present a risk of harm to the individual or to others. In these cases, a decision to use the medication may be quite reasonable, despite the potential increase in risk from the medication.

In the treatment of BPSD, atypical antipsychotic medications have the strongest evidence base for support. The Agency for Healthcare Research and Quality evaluated the off-label use of atypical antipsychotic agents in 2007.[7] They found "medium-level evidence" for the effectiveness of olanzapine, risperidone, and quetiapine to "reduce agitation and behavioral disturbances for people with dementia."

The American Psychiatric Association issued practice guidelines for the treatment of patients with Alzheimer's disease and other dementias in 2007.[8] The use of antipsychotics is supported in this guideline when non-pharmacologic strategies are inadequate. The guideline concludes, "On the basis of good evidence, antipsychotic medications are recommended for the treatment of psychosis in patients with dementia and for the treatment of agitation. These medications have also been shown to provide modest improvement in behavioral symptoms in general."

3. *The standards for use of unnecessary drugs in nursing homes, issued by the Centers for Medicare & Medicaid Services, are considered general guidelines and not absolute rules. Use of medications outside these standards may be appropriate in some cases.*

The Centers for Medicare & Medicaid Services (CMS) is responsible for enforcing federal laws relating to the quality of care provided to nursing facility residents. CMS issues federal regulations and accompanying interpretive guidelines (referred to as the State Operations Manual) for use by survey agencies in enforcing compliance on the part of nursing homes.

These regulations and guidelines include principles for use of medications in nursing facility residents. Guidelines for the use of antipsychotic medications in nursing facility residents are included in the State Operations Manual. These guidelines are based on evidence from the medical literature, and were extensively reviewed by experts prior to implementation.

While these guidelines are generally applicable and appropriate, CMS recognizes the complexity of caring for frail elderly individuals and permits use of medications outside these general guidelines. Clinicians are expected to document a rationale when medications are used outside the CMS guidelines.

4. *Although the OIG report did not address alternatives to the use of atypical antipsychotics for the treatment of behavioral and psychological symptoms of dementia (BPSD), non-pharmacological approaches are generally preferred as initial therapy when possible.*

Environmental modifications and non-pharmacological approaches are generally preferred as initial therapy for management of BPSD.[9-11] Clinical trials of non-pharmacologic therapy (e.g. music therapy, pet therapy, massage, aromatherapy) have been mixed and of limited value.[12] Because of funding limitations, these trials tend to be small in size and extrapolation of the results may not be appropriate. It is also difficult to randomize patients to a blinded study because the nature of the interventions require participants (including facility staff) to be aware of interventions.

In the nursing home setting, limitations on number and training of facility staff, along with high turnover of personnel, serve as barriers to use of non-pharmacologic interventions. These interventions require trained staff, can be time-consuming to employ, and must be individualized to the needs and nature of the resident problems.

Nursing homes have evolved to the point where the vast majority of residents have one or more mental health problems, yet few nursing homes have staff with specialized training in psychology or behavior management. The result is that medications have become the dominant approach to management of BPSD.

5. *The medication should be indicated, effective, safe, and used correctly by the patient.*

This principle is included in the creed of the consultant and senior care pharmacist, published by the American Society of Consultant Pharmacists in 2004.[13]

Consultant and Senior Care Pharmacist's Creed:

- I hold my patients' interests above all others.
- I take responsibility for my patients' medication-related needs.
- I ensure that my patients' medications are the most appropriate, the most effective available, the safest possible, and are used correctly.
- I identify, resolve, and prevent medication-related problems that may interfere with the goals of therapy.

Position

The American Society of Consultant Pharmacists supports the use of environmental modifications and non-pharmacologic approaches as initial therapy for the management of behavioral and psychological symptoms of dementia.

When deemed necessary and appropriate, the use of antipsychotics in nursing facility residents should include:

- An appropriate indication for use
- A specific and documented goal of therapy
- Ongoing monitoring of the resident to evaluate effectiveness in achieving the therapy goal and the development or presence of adverse effects from the medication
- Use of the medication only for the duration needed, and at the lowest effective dose

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