

Informed Consent for Atypical Antipsychotic Drug Use in Dementia Residents

Dear Decision Maker,

As the Medical Director for _____ Nursing Home I am writing to discuss the use of certain medications for your family member. These medications are called antipsychotics. These drugs are approved by the FDA for several indications including schizophrenia, manic depression/bipolar disorder, Tourette's syndrome and Huntington's disease.

Atypical antipsychotics are not approved for treatment of dementia, without the aforementioned medical diagnoses. Alzheimer's dementia and vascular dementia (from hypertension/strokes) are the two most common dementias within the nursing home settings. Dementia is a loss of cognition characterized by memory deficits; comprehension deficits; and unsettling emotional and psychological behaviors. At times the person with dementia may be agitated (screaming out, crying or laughing for no apparent reason), combative (striking out) with necessary daily care (bathing, dressing, toileting, incontinent care, eating). Behaviors observed may include pushing away a caregiver while they are assisting the resident with feeding, or showing irritation toward a fellow resident whom is in close proximity (walking down a hallway, or sitting next to each other in the dining hall).

Facility staff are educated to address these behaviors with non-drug interventions. Residents behaviors are assessed for possible causes: physical conditions or needs (pain, infections, illness, dehydration, constipation, medication side effects); psychological conditions or needs (loneliness, boredom, anxiety, worry, fear, emotional state, depression, delirium, psychosis, and mental illness); and environmental causes (noise, lightening, odors, caregivers actions/appearance/approach). In addition, the residents are evaluated by an in house psychiatric consultant who examines the resident and evaluates their psychological issues making recommendations. It is the goal of the facility staff to meet these needs in an attempt to resolve behaviors that affect the resident's ability to function at their highest practical level of well-being.

If facility staff are unable to treat the above behaviors with the approaches listed (behavior modification, music therapy, re-directing activities, aroma therapy, pet therapy), antipsychotic medications may be indicated. Examples of these medications are aripiprazole (Abilify), risperidone (Risperdal), quetiapine (Seroquel), or olanzapine (Zyprexa). These medications, if warranted, would always be started at the lowest possible dose and be monitored daily for adverse side effects. The justifications for these medications include resident presents with one or more of the following issues:

- The resident presents a danger to themselves or others
- Inconsolable or persistent distress
- Substantial difficulty in receiving necessary physical care
- A significant decline in function

These medications can have adverse effects in some residents; research has indicated a slight increase in the number of heart attacks, strokes and death in relations to these medications. The FDA has recommended these drugs not be used in the elderly dementia patient and the Centers for Medicare & Medicaid Services (CMS) is working to decrease the use of these drugs in nursing homes. CMS has launched an initiative aimed at improving behavioral health and safe guarding residents in nursing homes from unnecessary antipsychotic medications.

FDA BLACK BOX WARNINGFOR ANTIPSYCHOTIC MEDICATIONS

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA_RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (model duration of 10 weeks) largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10 week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infections (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear.

The primary doctor and the Medical Director have reviewed your family member’s medical condition. They will or have attempted a gradual dose reduction with the foal of discontinuing these medications. We ask you to complete the consent form attached indicating your preference regarding antipsychotic medication use.

Any resident who remains on antipsychotic medications if clinically indicated (potential benefit of drug outweighs above risks) will continue to have gradual dose reductions and be monitored for adverse side effects of these medications.

Thank you,

Dr. _____

**RISK VERSUS BENEFIT OF THE USE OF CERTAIN MEDICATION FOR DEMENTIA RESIDENTS
AND THEIR AGENTS**

I have been given a copy of the letter addressing the benefit and risk to (resident name)

_____.

Medication _____ Current dosage _____

My Signature indicates the following:

- I understand the information contained in the letter and have no further questions.
- I DO want to continue the use of antipsychotic medication. Initial
- I DO NOT want to continue the use of antipsychotic medication. Initial

PRINT NAME AND DECISION MAKING AUTHORITY

SIGNATURE OF DECISION MAKER

SIGNATURE OF FACILITY NURSE/PHYSICIAN

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