

Antipsychotic Medication Consent for Off-Label Use

Residents have a right to live in an environment of dignity, comfort and independence without being over medicated. Antipsychotics in nursing homes are *only* approved for Schizophrenia, Huntingtons or Tourettes. All other use must be to promote safety and allow for the best possible physical, mental and psychosocial functioning, or if the behaviors pose a risk to the resident or others. Such use is considered "off-label", particularly Behavioral or Psychological Symptoms of Dementia (BPSD).

Use of antipsychotics may hasten death or serious problems (see **Box Warning**, below). They may not be used indefinitely without defensible reasons. By federal regulations, providers must try to taper or discontinue them regularly or document evidence indicating why they believe that doing so would likely cause an imminent, significant clinical decline or place other persons at risk. A list of antipsychotics and their potential side effects may be found on the reverse of this form.

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** compared to placebo. Analyses of 17 placebo controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen 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 infectious (e.g., pneumonia) in nature.

[THIS DRUG] is not approved for the treatment of patients with Dementia-Related Psychosis.

The *intended benefit* is usually to calm or decrease fears and protect patients or others from harm as a consequence of unprovoked agitated behaviors. Off-label use may help patients with psychotic behaviors due to dementia, though **this must be evaluated and documented frequently.**

_____ (Resident) is on _____ for the following behavior(s):

A **beneficial** response would be:

and will be evaluated within 1-2 months. If there is no improvement or adverse effects emerge, the dose will be changed or it may be deemed ineffective or dangerous and need to be tapered and/or discontinued.

Consent of Provider and Patient / MDPOA: The intended benefits of using the antipsychotic medication(s) above outweigh potential risks **and have been discussed by me with the patient or their decision-maker.** It is in the resident's best interest to continue use while tracking benefits or psychotic behaviors placing them or others at risk.

I will comply with Federal Regulations intended to protect patients from use of unnecessary medications, including mandatory Gradual Dose Reductions as appropriate when the resident's documented psychotic behaviors do not present potential for harm to themselves or others.

Physician or Provider; Credentials (Print)

Signature

___/___/201___

Patient or MDPOA; Relationship to Patient (Print)

Signature

___/___/201___

This consent should be updated **ANNUALLY** and with any **significant change in condition or drugs.**

Federal Regulations mandate Gradual Dose Reductions and/or attempts to discontinue these agents on a prescribed timetable **or** documentation must be provided explaining why the patient or others would likely be in imminent clinical danger if this were attempted.

Though risks are not identical for each drug and some are more likely to cause some problems than others, below is a more complete list of potential serious and common side effects reported with most of these medications.

Antipsychotic Medications:

- Olanzapine (Zyprexa)
- Aripiprazole (Abilify)
- Risperidone (Risperdal)
- Quetiapine (Seroquel)
- Clozapine (Clozaril)
- Ziprasidone (Geodon)
- Haloperidol (Haldol)*
- Thioridazine (Mellaril)*
- Chlorpromazine (Thorazine)*
- Prochlorperazine (Compazine)*
- Loxapine (Loxitane)*
- Molindone (Moban)
- Thiothixene (Navane)*
- Pimozide (Orap)*
- Mesoridazine (Serentil)
- Fluphenazine (Prolixin)*
- Trifluoperazine (Stelazine)*
- Promazine (Sparine)*
- Triflupromazine (Vesprin)*
- Iloperidone (Fanapt)
- Lurasidone (Latuda)
- Perphenazine (Trilafon)*
- Clozapine (FazaClo)
- Paliperidone (Invega)
- Brexpiprazole (Rexulti)

**First Generation Antipsychotics; all others would be considered 'Second Generation Antipsychotics'*

Potential Side Effects of Antipsychotics – First Generation

Serious:	Extrapyramidal Symptoms, Severe Hyperpyrexia / Fever Neuroleptic Malignant Syndrome QT Prolongation / EKG Changes Sudden Death Withdrawal (if abruptly stopped) Agranulocytosis (No White Blood Cells) Retinopathy Dermatitis	Tardive Dyskinesia Heat Stroke Hypotension (Low Blood Pressure) Torsades de Pointes Hyponatremia (Low Blood Sodium) Hepatic Impairment (Liver Failure) Cataracts Cerebral Edema Lupus Erythematosus	Dystonia Pneumonia Hypertension (High Blood Pressure) Cardiac Arrhythmias Seizures Leukopenia (Low White Blood Cells) Neutropenia Anemia Parkinson Disease
Common:	Extrapyramidal Symptoms Insomnia / Drowsiness / Lethargy Anticholinergic Effects Galactorrhea Nausea / Anorexia Swelling Constipation Itching / Skin Redness	Tardive Dyskinesia Anxiety Falls / Fractures Menstrual Irregularities Heartburn Depression Dry Mouth / Cracked Lips Fast Heart Rate	Akathisia (Restlessness) Weight Changes Gynecomastia / Breast Tenderness Photosensitivity Headache Impotence Urinary Retention Nasal Congestion

Potential Side Effects of Antipsychotics – Second Generation

Serious:	Extrapyramidal Symptoms, Severe Hyperpyrexia / Fever Neuroleptic Malignant Syndrome Torsades de Pointes Leukopenia/Neutropenia (Few White Blood Cells) Passing Out / Syncope Hyperglycemia (High Blood Sugar) Dysphagia, Severe (Trouble Swallowing) Rhabdomyolysis (Muscle Tissue Death) Cholecystitis (Gallstones / Biliary Inflammation) Blood Dyscrasias (Bad Blood Counts) Hyperkalemia (High Blood Potassium) Myocarditis (Inflammation of Heart)	Tardive Dyskinesia Stroke / TIA Hypotension (Low Blood Pressure) Sudden Cardiac Death Tachycardia (Fast Heart Rate) Bradycardia (Slow Heart Rate) Intestinal Obstruction Hemorrhage (Bleeding) Paralytic Ileus Hypokalemia (Low Blood Potassium) Pulmonary Embolus Cardiomyopathy (Heart Disease)	Dystonia Heat Stroke Hypertension (High Blood Pressure) Seizures Hepatitis Suicide Diabetes Aspiration Pancreatitis Depression Glaucoma
Common:	Extrapyramidal Symptoms Akathisia (Restlessness) / Irritability Insomnia / Drowsiness / Lethargy / Fatigue Lightheadedness / Dizziness / Sedation Arthralgia (Joint pains) Nausea / Vomiting Blurred Vision Myalgia (Muscle pains) Visual Disturbances / Double Vision Insomnia (Difficulty Falling / Staying Asleep)	Headache Confusion Anxiety Falls / Fractures Cough / Colds Constipation Cough Excess Saliva High Cholesterol Bruising	Tardive Dyskinesia Tremor Weight Gain Swelling Dry, Cracked Lips Incontinence Sleep Disturbance Rash Paresthesias

If you have questions about these drugs or side effects, please contact the primary care provider or leave your question with the staff to be answered by the Medical Director, Psychiatrist or Consultant Pharmacist.