

## INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 04/16/2021

Completion of this form is voluntary. If informed consent is not given, the medication cannot be administered without a court order unless in an emergency.

This consent is maintained in the client's record and is accessible to authorized users.

Name – Patient / Client (Last, First MI)		ID Number	Living Unit	Date of Birth
Name – Individual Preparing This Form		Name – Staff Contact		Name / Telephone Number – Institution

MEDICATION CATEGORY	MEDICATION	RECOMMENDED DAILY TOTAL DOSAGE RANGE	ANTICIPATED DOSAGE RANGE
Antipsychotic / Bipolar Agent	Zyprexa oral tablet; Zyprexa Zydis oral disintegrating tablet; Zyprexa Intramuscular Injection; Zyprexa Relprevv Intramuscular Injection  (olanzapine)	Oral: 2.5 mg-50 mg with most doses in the 2.5 mg-20 mg range IM: 5 mg-10 mg per dose, up to 3 doses 24 hours Long Acting Injectable: 150 mg-300 mg IM every 2 weeks, 300 mg-405 mg IM every 4 weeks	

The anticipated dosage range is to be individualized, may be above or below the recommended range but no medication will be administered without your informed and written consent.

Recommended daily total dosage range of manufacturer, as stated in *Physician's Desk Reference* (PDR) or another standard reference.

This medication will be administered ☐ Orally ☐ Injection ☐ Other – Specify:

### 1. Reason for Use of Psychotropic Medication and Benefits Expected (note if this is 'Off-Label' Use)

Include DSM-5 diagnosis or the diagnostic impression ("working hypothesis.")

### 2. Alternative mode(s) of treatment other than OR in addition to medications include

Note: Some of these would be applicable only in an inpatient environment.

- |   |   |
|---|---|
| <input type="checkbox"/> Environment and/or staff changes           | <input type="checkbox"/> Rehabilitation treatments/therapy (OT, PT, AT)   |
| <input type="checkbox"/> Positive redirection and staff interaction | <input type="checkbox"/> Treatment programs and approaches (habilitation) |
| <input type="checkbox"/> Individual and/or group therapy            | <input type="checkbox"/> Use of behavior intervention techniques          |

Other Alternatives:

### 3. Probable consequences of NOT receiving the proposed medication are

Impairment of ☐ Work Activities ☐ Family Relationships ☐ Social Functioning

#### Possible increase in symptoms leading to potential

- |  |  |
|--|--|
| <input type="checkbox"/> Use of seclusion or restraint                   | <input type="checkbox"/> Limits on recreation and leisure activities |
| <input type="checkbox"/> Limits on access to possessions                 | <input type="checkbox"/> Intervention of law enforcement authorities |
| <input type="checkbox"/> Limits on personal freedoms                     | <input type="checkbox"/> Risk of harm to self or others              |
| <input type="checkbox"/> Limit participation in treatment and activities |  |

Other Consequences:

**Note:** These consequences may vary depending upon whether or not the individual is in an inpatient setting. It is also possible that in unusual situations, little or no adverse consequences may occur if the medications are not administered.

See Page 2

Client Initial \_\_\_\_\_ Date \_\_\_\_\_

4. Possible side effects, warnings, and cautions associated with this medication are listed below. This is not an all-inclusive list but is representative of items of potential clinical significance to you. For more information on this medication, you may consult further with your physician or refer to a standard text, such as the PDR. As part of monitoring some of these potential side effects, your physician may order laboratory or other tests. The treatment team will closely monitor individuals who are unable to readily communicate side effects in order to enhance care and treatment.

Continued – Possible side effects, warnings, and cautions associated with this medication.

**Most Common Side Effects:** abnormal walking or balance; clumsiness; headache; constipation; dizziness; dizziness or fainting when getting up suddenly from a lying or sitting position (orthostatic hypotension); drowsiness; dry mouth; sleepiness or unusual drowsiness; unsteadiness; weakness; weight gain/increased appetite; elevated cholesterol, elevated glucose, elevated prolactin levels; injection site reaction; agitation; behavior problems; difficulty in speaking or swallowing; restlessness or need to keep moving; stiffness of arms or legs; trembling or shaking of hands and fingers; peripheral edema.

**Less Common Side Effects:** changes in vision; chest pain; fever; flu-like symptoms; difficulty speaking; runny nose; lip smacking or puckering; mood or mental changes such as anger, anxiety, giddiness, loss of memory, or nervousness; muscle spasms of face, neck, and back; personality disorder; muscle twitching or jerking; nervousness; puffing of cheeks; rapid or worm-like movements of tongue; rhythmic movement of muscles; slow or fast heartbeat; swelling of feet or ankles; twitching movements; twitching, twisting, uncontrolled repetitive movements of tongue, lips, face, arms, or legs; uncontrolled chewing movements; uncontrolled jerking or twisting movements of hands, arms and legs; uncontrolled movements of lips, tongue, or cheeks; unusual or incomplete body or facial movements; unable to achieve orgasm; delayed or impaired ejaculation; decreased sexual interest or function; changes with menstruation; development of breasts in males; falling; cough; loss of bladder control; abdominal pain; diarrhea; gas; vaginal discharge; increased risk of viral infection; abnormal dreams; joint pain; muscle stiffness; tremor.

**Rare Side Effects:** Although rare, contact your doctor as soon as possible if any of the following side effects occur: pounding or abnormal heartbeat; hair loss; warmth or fever; increased sensitivity of the skin to the sun; heavy menstrual bleeding; bloating; intestinal obstruction; nausea; difficulty with urination; swelling of the tongue, lips, or face; slurring of words or mumbling; confusion; chills; coma; joint pain; hangover effect; seizure; changed or poor posture; new or worsening thoughts of suicide; bone pain or fractures; frequent urination; difficulty breathing; rash or hives; fainting; painful, long lasting erection; yellowing of the eyes or skin; development of lesions or bumps on the skin; muscle pain; delirium.

#### Caution:

- **Extrapyramidal symptoms (EPS)**

Patients have reported muscle spasms of the neck and back; shuffling walk; tic-like (jerky) movements of the head, face and neck; trembling and shaking of the hands and fingers; inability to move eyes; mask-like face; loss of balance control; blurred vision; difficulty speaking or swallowing. Additionally, though not common, Tardive Dyskinesia has been reported. Tardive Dyskinesia presents with lip smacking or puckering, puffing of cheeks, rapid or fine worm-like movement of tongue, uncontrolled chewing movement, or uncontrolled movements of arms and legs may occur and may not go away after stopping use of the medication.

- **Neuroleptic Malignant Syndrome (NMS)**

Use may be associated with NMS. Monitor for changes in thinking, fever, muscle stiffness, and/ autonomic instability (unable to exercise, abnormal sweating, loss of appetite, loss of bladder control, difficulty with ejaculation, blurry vision). Call your doctor as soon as possible if you believe you may have NMS.

- **QT prolongation**

This drug has the potential to prolong the QT interval of the heart. Caution should be exercised by those who have a history of QT prolongation, heart syndromes such as Congenital Long QT Syndrome (CLQTS), or by those who have multiple risk factors for QT prolongation.

- **Driving and operating heavy machinery**

Olanzapine may cause drowsiness or dizziness, which could make driving, operating heavy machinery, or participating in other activities requiring alertness dangerous. Be sure you know how this medication affects you before participating in these activities.

- **Blood disorder**

Check with your doctor immediately if you develop fever, chills, sore throat, or sores in the mouth. These may be signs of a very serious blood problem that has occurred rarely in patients taking olanzapine. This medication also has the potential to increase bleeding/

- **Orthostatic hypotension**

Orthostatic hypotension is when one feels dizzy while getting up from a lying or sitting position. Getting up slowly may help. If this problem continues or gets worse, check with your doctor.

- **Fall risk**

This medication increases the risk of experiencing a fall due to drowsiness and dizziness. Caution should be exercised by those who have a history of falls.

- **Weight gain**

This medication has been associated with increased appetite and weight gain.

- **Seizure**

This medication may, in rare cases, cause individuals to experience a seizure. Caution should be exercised in those who have a history of seizures.

- **Suicide**

This medication has the potential to cause new or worsening thoughts of suicide. If you experience these, immediately call your doctor.

- **Withdrawal**

This medication should not be suddenly stopped as it may cause an individual to experience symptoms of withdrawal. Please speak with your physician before stopping this medication.

- **Anticholinergic effects**

May cause symptoms such as confusion, agitation, constipation, dry mouth, blurred vision, or difficulty urinating.

**Warning: [Black Box 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 17 placebo-controlled trials (modal duration, 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients between 1.6 and 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 approximately 4.5%, compared with 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 (eg, heart failure, sudden death) or infectious (eg, 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 patient is not clear. Olanzapine is not approved for treatment of patients with dementia-related psychosis.

**Warning: [Black Box Warning]: Postinjection delirium/sedation syndrome (Zyprexa Relprevv):** Adverse reactions with signs and symptoms consistent with olanzapine overdose, in particular, sedation (including coma) and/or delirium, have been reported following injections of olanzapine extended release (ER). Olanzapine ER must be administered in a registered health care facility with ready access to emergency response services. After each injection, patients must be observed at the health care facility by a health care provider for at least 3 hours. Because of this risk, olanzapine ER is available only through a restricted distribution program called Zyprexa Relprevv Patient Care Program, and requires health care provider, health care facility, patient, and pharmacy enrollment.

See standard reference text for an all-inclusive list of side effects.

**By my signature below, I GIVE consent for the named medication on Page 1 and anticipated dosage range. My signature also indicates that I understand the following:**

1. I can refuse to give consent or can withdraw my consent at any time with written notification to the institution director or designee. This will not affect my right to change my decision at a later date. If I withdraw consent after a medication is started, I realize that the medication may not be discontinued immediately. Rather, it will be tapered as rapidly as medically safe and then discontinued so as to prevent an adverse medical consequence, such as seizures, due to rapid medication withdrawal.
2. Questions regarding this medication can be discussed with the Interdisciplinary Team, including the physician. The staff contact person can assist in making any necessary arrangements.
3. Questions regarding any behavior support plan or behavior intervention plan, which correspond with the use of the medication, can be directed to the client's social worker, case manager, or psychologist.
4. I have the right to request a review at any time of my record, pursuant to § 51.30(4)(d) or § 51.30(5)(b).
5. I have a legal right to file a complaint if I feel that client rights have been inappropriately restricted. The client's social worker, case manager, or agency/facility client rights specialist may be contacted for assistance.
6. My consent permits the dose to be changed within the **anticipated dosage range** without signing another consent.
7. I understand the reasons for the use of the medication, its potential risks and benefits, other alternative treatment(s), and the probable consequences that may occur if the proposed medication is not given. I have been given adequate time to study the information and find the information to be specific, accurate, and complete.
8. This medication consent is for a period effective immediately and not to exceed fifteen (15) months from the date of my signature. The need for and continued use of this medication will be reviewed at least quarterly by the Interdisciplinary Team. The goal, on behalf of the client, will be to arrive at and maintain the client at the minimum effective dose.

**SIGNATURES****DATE SIGNED**

Client – If Presumed Competent to Consent/Parent of Minor/Guardian (POA-HC)	Relationship to Client <input type="checkbox"/> Self <input type="checkbox"/> Parent <input type="checkbox"/> Guardian (POA-HC)	
Staff Present at Oral Discussion	Title	
Client / Parent of Minor / Guardian (POA-HC) Comments		

**As parent/guardian (POA-HC) was not available for signature, he/she was verbally informed of the information in this consent.**

**Verbal Consent**

Obtained by – PRINT – Staff Name	Date Obtained	Written Consent Received <input type="checkbox"/> Yes <input type="checkbox"/> No
Obtained from – PRINT – Parent / Guardian (POA-HC) Name	Date Expires	Date Received