DEPARTMENT OF HEALTH SERVICES
Division of Care and Treatment Services
F-24277 (05/2024)

STATE OF WISCONSIN
42 CFR483.420(a)(2)
DHS 134.31(3)(o)
DHS 94.03 & 94.09
§§ 51.61(1)(g) & (h)

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 10/06/2021

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
Antidepressant (tricyclic)	Anafranil (clomipramine)	Adult 25mg – 250mg Children older than 10 years of age, 20-30mg with gradual dosage increase as needed – MAX 200 mg/day or 3mg/kg/day (whichever is less)	

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.

☐ Environment and/or staff changes
☐ Positive redirection and staff interaction
☐ Individual and/or group therapy
☐ Rehabilitation treatments/therapy (OT, PT, AT)
☐ Treatment programs and approaches (habilitation)
☐ 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

☐ Use of seclusion or restraint
☐ Limits on access to possessions
☐ Limits on personal freedoms
☐ Limit participation in treatment and activities
☐ Limits on recreation and leisure activities
☐ Intervention of law enforcement authorities
☐ Risk of harm to self or others

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: dizziness; drowsiness; dryness of mouth; headache; loss of appetite; nausea; tiredness or weakness (mild); weight gain; constipation; tremor.

Less Common Side Effects: diarrhea; heartburn; trouble sleeping; muscle pain or weakness.

Rare Side Effects: Check with your doctor immediately if any of the following side effects occur: blurred vision; confusion or delirium; constipation (severe, especially in the elderly); decreased sexual ability; difficulty in speaking or swallowing; eye pain; fainting; fast or irregular heartbeat (pounding, racing, skipping); hallucinations; loss of balance control; nervousness or restlessness; problems in urinating; shakiness or trembling; shuffling walk; slowed movements; stiffness of arms and legs; rash; swelling of face, tongue or throat; seizures; ringing in the ears; yellow eyes or skin; stomach pain; worsening of mood or behavior; thoughts of suicide.

Caution

- **Withdrawal**
  This medication should not be discontinued abruptly. Please speak with your doctor before stopping this medication.

- **Seizure**
  Caution should be used in administering clomipramine to patients with a history of seizures or other predisposing factors, e.g., brain damage of varying etiology, alcoholism, and concomitant use with other drugs that lower the seizure threshold.

- **Serotonin Syndrome**
  Potentially life-threatening serotonin syndrome has been reported with SNRIs and SSRIs, including clomipramine, alone but particularly with concomitant use of other serotonergic drugs (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort) and with drugs that impair metabolism of serotonin (in particular, MAOIs, both those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue). The use of clomipramine with MAOIs intended to treat psychiatric disorders is contraindicated. If use of clomipramine with serotonergic drugs is needed, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases. Discontinue treatment (and any concomitant serotonergic agent) immediately if signs/symptoms arise.

- **Eosinophilia and Systemic Symptoms (DRESS)**
  Rare cases of drug rash with eosinophilia and systemic symptoms (DRESS) have been reported with the use of clomipramine. If a severe acute reaction occurs, discontinue clomipramine therapy immediately.

Warning: [Black Box Warning]: Suicidality and Antidepressant Drugs.
Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in short term studies in children, adolescents, and young adults with major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of this drug or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and care givers should be advised of the need for close observation and communication with the prescriber. Clomipramine is not approved for use in pediatric patients.

MONITORING RECOMMENDATIONS RELATED TO BLACK BOX DATA
—Close observation for suicidal thinking or unusual changes in behavior

Warning: These medications could be very dangerous if taken in large doses. Symptoms of overdose include convulsions (seizures); dizziness (severe); drowsiness (severe); fast or irregular heartbeat; fever; muscle stiffness or weakness (severe); restlessness or agitation; trouble in breathing; vomiting.

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

Client Initial _____ Date _____

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 ☐ Self ☐ Parent ☐ 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 ☐ Yes ☐ No
Obtained from – PRINT – Parent / Guardian (POA-HC) Name	Date Expires	Date Received

Client Initial _____ Date _____