DEPARTMENT OF HEALTH SERVICES
Division of Care and Treatment Services
F-24277 (09/2016)

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 08/09/2018

Completion of this form is voluntary. If not completed, 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
Anticonvulsant / Mood Stabilizing Agent	Tegretol (carbamazepine)	200mg –1600mg/day maximum May dose according to blood levels.	

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 "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
The most common side effects include dizziness, drowsiness, headache, nausea/vomiting, unintentional body movements, constipation, dry mouth, itch/rash, and blurred vision.

Less Common Side Effects
Less common side effects include repetitive uncontrollable eye movements, changes in blood pressure,speech disturbance, twitching, weakness, behavioral changes (especially in children), confusion, agitation, diarrhea, hives, aching joints or muscles, increased sensitivity of skin to sunlight, loss of appetite, stomach pain or discomfort.

Rare Side Effects
Rare but serious side effects include blood in urine or stool, nosebleeds or other unusual bleeding or bruising, electrolyte changes, congestive heart failure, a serious rash called Stevens Johnson Syndrome or Toxic Epidermal Necrolysis, suicidal behavior or ideation, pancreatitis, change in seizures, bone marrow suppression and other effects on blood cell counts, liver failure or toxicity causing yellowing of skin/eyes, kidney failure, pulmonary hypersensitivity, fever or infection, irregular, pounding, or unusually slow heartbeat, mental depression with restlessness and nervousness or other mood or mental changes, ringing, buzzing, or other unexplained sounds in the ears, visual hallucinations, change in eyesight, sudden decrease in amount of urine, swelling of face, hands, feet, or lower legs.

Caution
Notify physician if mood/mental changes,signs of an allergic reaction,swelling of extremities, difficulty urinating and/or shortness of breath occur.

Patients should be advised that anaphylactic reactions and angioedema may occur during treatment with Tegretol. Advise patients to immediately report signs and symptoms suggesting angioedema (swelling of the face, eyes, lips, or tongue, or difficulty in swallowing or breathing) and to stop taking the drug until they have consulted with their healthcare provider.

Warning
BLACK BOX WARNING
Hematological
Aplastic anemia and agranulocytosis has been reported with use of carbamazepine. Risk is 5-8 times greater than general population. However, the overall risk of these reactions in the untreated general population is low. Agranluocytosis: 6 patients/1 million population per year. Aplastic anemia: 2 patients/1 million population per year. Incidence data: Although reports of transient or persistent decreased platelet or white blood cell counts are not uncommon with carbamazepine use, data are not available to estimate accurately their incidence or outcome. Outcomes: The vast majority of the cases of leukopenia have not progressed to the more serious conditions of aplastic anemia or ganulocytosis.

Serious Dermatologic Reactions and HLA-B*1502 Allele
Serious and sometimes fatal dermatologic reactions, including toxic epidermal necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), have been reported during treatment with carbamazepine. These reactions are estimated to occur in 1 to 6 per 10,000 new users in countries with mainly caucasian populations, but the risk in some Asian countries is estimated to be about 10 times higher. Studies in patients of Chinese ancestry have found a strong association between the risk of developing SJS/TEN and the presence of HLA-B*1502, an inherited allelic variant of the HLA-B gene. HLA-B*1502 is found almost exclusively in patients with ancestry across broad areas of Asia. Patients with ancestry in genetically at risk populations should be screened for the presence of HLA-B*1502 prior to initiating treatment with carbamazepine. Patients testing positive for the allele should not be treated with carbamazepine unless the benefit clearly outweighs the risk.

MONITORING RECOMMENDATIONS RELATED TO BLACK BOX DATA
Note: The following recommendations are part of the black box warning data.

Discontinuation of medication should be considered if any evidence of significant bone marrow depression develops. Because of the very low incidence of agranulocytosis and aplastic anemia the vast majority of minor hematologic changes observed during monitoring are unlikely to signal the development of either event.

The following recommendations are outlined in the Laboratory Test section of the package insert:

Perform complete pretreatment blood counts (including platelets and possibly reticulocytes and serum iron) and periodic monitoring through therapy. If low or decreased white blood cell count or platelet counts occur, monitor patient closely.

See PDR for an all-inclusive list of side effects.

Medication: Tegretol – (carbamazepine)

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 _____