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 06/08/2017

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	Trileptal (oxcarbazepine)	300mg - 2400mg	

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

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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

Check with your doctor as soon as possible if any of the following side effects occur: change in vision; change in walking or balance; clumsiness or unsteadiness; cough, fever, sneezing, or sore throat; crying; dizziness; double vision; false sense of well-being; feeling of constant movement of self or surroundings; mental depression; sensation of spinning; uncontrolled back-and-forth and/or rolling eye movements.

Other more common possible side effects may include: abdominal pain; burning feeling in chest or stomach; nausea and vomiting; runny or stuffy nose; sleepiness or unusual drowsiness.

Less Common Side Effects

Check with your doctor as soon as possible if any of the following less common side effects occur: agitation; awkwardness; bloody or cloudy urine; blurred vision; bruising; confusion; congestion; convulsions (seizures); decreased urination; difficulty in focusing eyes; disorientation; faintness or light-headedness when getting up from a lying or sitting position; fast or irregular heartbeat; frequent falls; frequent urge to urinate; general feeling of illness; headache; hoarseness; increased thirst; itching of the vagina, with or without white vaginal discharge; loss of consciousness; memory loss; muscle cramps; pain or burning while urinating; pain or tenderness around eyes or cheekbones; poor control in body movements; problems with coordination; shaking or trembling of arms, legs, hands, and feet; shortness of breath; skin rash; stuffy or runny nose; tightness in chest; trouble in walking; troubled breathing; unusual feelings; unusual tiredness or weakness; wheezing.

Other less common side effects may include: acid or sour stomach; acne; back pain; belching; bloody nose; blurred vision; change in your sense of taste; constipation; diarrhea; difficulty in speaking; dryness of mouth; feeling of warmth and redness of face, neck, arms, and occasionally chest; heartburn; increased sweating; increased urination; nervousness; trouble in sleeping.

Rare Side Effects

Although rare, check with your doctor as soon as possible if any of the following side effects occur: anxiety; bleeding or crusting sores on lips; burning feeling in chest or stomach; chest pain; chills; decreased response to stimulation; hives or itching; irritability; joint pain; muscle pain or weakness; nervousness; purple spots on skin; rectal bleeding; redness, blistering, peeling, or loosening of skin; restlessness; sores, ulcers, or white spots in mouth or on lips; stomach upset; swelling of legs; swollen glands.

Caution

Do not take other medicines unless they have been discussed with your doctor. This medicine will add to the effects of alcohol and other CNS depressants (medicines that make you drowsy or less alert).

This medicine may cause some people to become drowsy, dizzy, or less alert than they are normally. Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are dizzy or are not alert.

Oral contraceptives (birth control pills) containing estrogen or progestin, contraceptive progestin injections (e.g., Depo-Provera), and implant contraceptive forms of progestin (e.g., Norplant) may not work properly if you take them while you are taking oxcarbazepine. Unplanned pregnancies may occur. You should use a different or additional means of birth control while you are taking oxcarbazepine.

Dizziness, lightheadedness, or fainting may occur, especially when you get up from a lying or sitting position. Getting up slowly may help.

Warning

Hyponatremia

Clinically significant hyponatremia (sodium <125 mmol/L) can develop during Trileptal® (oxcarbazepine) use. In the 14 controlled epilepsy studies, 2.5% of Trileptal-treated patients (38/1,524) had a sodium of less than 125 mmol/L at some point during treatment, compared to no such patients assigned placebo or active control (carbamazepine and phenobarbital for adjunctive and monotherapy substitution studies, and phenytoin and valproate for the monotherapy initiation studies). Clinically significant hyponatremia generally occurred during the first three months of treatment with Trileptal, although there were patients who first developed a serum sodium <125 mmol/L more than one year after initiation of therapy. Most patients who developed hyponatremia were asymptomatic but patients in the clinical trials were frequently monitored and some had their Trileptal dose reduced, discontinued, or had their fluid intake restricted for hyponatremia. Whether or not these maneuvers prevented the occurrence of more severe events is unknown. Cases of symptomatic hyponatremia have been reported during post-marketing use. In clinical trials, patients whose treatment with Trileptal was discontinued due to hyponatremia generally experienced normalization of serum sodium within a few days without additional treatment. Measurement of serum sodium levels should be considered for patients during maintenance treatment with Trileptal, particularly if the patient is receiving other medications known to decrease serum sodium levels (for example, drugs associated with inappropriate ADH secretion) or if symptoms possibly indicating hyponatremia develop (e.g., nausea, malaise, headache, lethargy, confusion, obtundation, or increase in seizure frequency or severity).

Anaphylactic Reactions and Angioedema.

Rare cases of anaphylaxis and angioedema involving the larynx, glottis, lips and eyelids have been reported in patients after taking the first or subsequent doses of Trileptal. Angioedema associated with laryngeal edema can be fatal. If a patient develops any of these reactions after treatment with Trileptal, the drug should be discontinued and an alternative treatment started. These patients should not be rechallenged with the drug.

Patients with a Past History of Hypersensitivity Reaction to Carbamazepine:
Patients who have had hypersensitivity reactions to carbamazepine should be informed that approximately 25%-30% of them will experience hypersensitivity reactions with Trileptal. For this reason patients should be specifically questioned about any prior experience with carbamazepine, and patients with a history of hypersensitivity reactions to carbamazepine should ordinarily be treated with Trileptal only if the potential benefit justifies the potential risk. If signs or symptoms of hypersensitivity develop, Trileptal should be discontinued immediately.

Multi-Organ Hypersensitivity:
Serious dermatological reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in both children and adults in association with Trileptal use. The median time of onset for reported cases was 19 days. Such serious skin reactions may be life threatening, and some patients have required hospitalization with very rare reports of fatal outcome. Recurrence of the serious skin reactions following rechallenge with Trileptal has also been reported. The reporting rate of TEN and SJS associated with Trileptal use, which is generally accepted to be an underestimate due to underreporting, exceeds the background incidence rate estimates by a factor of 3- to 10-fold. Estimates of the background incidence rate for these serious skin reactions in the general population range between 0.5 to 6 cases per million-person years. Therefore, if a patient develops a skin reaction while taking Trileptal, consideration should be given to discontinuing Trileptal use and prescribing another antiepileptic medication.

Suicidal Behavior and Ideation
Antiepileptic drugs (AEDs), including Trileptal, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Pooled analyses of 199 placebo-controlled clinical trials (mono- and adjunctive therapy) of 11 different AEDs showed that patients randomized to one of the AEDs had approximately twice the risk (adjusted Relative Risk 1.8, 95% CI:1.2, 2.7) of suicidal thinking or behavior compared to patients randomized to placebo. In these trials, which had a median treatment duration of 12 weeks, the estimated incidence rate of suicidal behavior or ideation among 27,863 AED-treated patients was 0.43%, compared to 0.24% among 16,029 placebo-treated patients, representing an increase of approximately one case of suicidal thinking or behavior for every 530 patients treated. There were four suicides in drug-treated patients in the trials and none in placebo-treated patients, but the number is too small to allow any conclusion about drug effect on suicide. The increased risk of suicidal thoughts or behavior with AEDs was observed as early as one week after starting drug treatment with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed. The risk of suicidal thoughts or behavior was generally consistent among drugs in the data analyzed. The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. The risk did not vary substantially by age (5-100 years) in the clinical trials analyzed
Drug Patients with The relative risk for suicidal thoughts or behavior was higher in clinical trials for epilepsy than in clinical trials for psychiatric or other conditions, but the absolute risk differences were similar for the epilepsy and psychiatric indications.
Anyone considering prescribing Trileptal or any other AED must balance the risk of suicidal thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during treatment, the prescriber needs to consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.
Patients, their caregivers, and families should be informed that AEDs increase the risk of suicidal thoughts and behavior and should be advised of the need to be alert for the emergence or worsening of the signs and symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Behaviors of concern should be reported immediately to healthcare providers.

Withdrawal of AEDs
As with all antiepileptic drugs, Trileptal should be withdrawn gradually to minimize the potential of increased seizure frequency.

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

Client Initial _____ Date _____

Medication: Trileptal - (oxcarbazepine)

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 _____