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 05/27/2021

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
Anticonvulsant	Gabitril (tiagabine)	4 mg-56 mg	

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.

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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: dizziness, drowsiness, nervousness, loss of concentration, nausea, increased risk of infections; weakness; tremor; accidental injury from clumsiness.

Less Common Side Effects: abdominal pain; flushing; impaired vision; increased appetite; increased cough; mouth ulcers; muscle weakness; nausea; pain; difficulty falling asleep or staying asleep; burning, numbness, or tingling sensations; confusion; itching; mental depression; speech or language problems; altered balance; difficulty walking; increased involuntary movements; rash; urinary tract infections; altered memory; ear ringing; altered vision; vomiting; diarrhea; hair loss; dry skin; flu-like symptoms.

Rare Side Effects: Check with your doctor as soon as possible if you experience any of the following: agitation; bloody or cloudy urine; burning, pain, or difficulty urinating; frequent urge to urinate; severe generalized weakness; hostility; memory problems; quick to react or overreact emotionally; rash; uncontrolled back-and-forth and/or rolling eye movements; walking in unusual manner; signs of an allergic reaction (swelling of the face, lips, or tongue; difficulty breathing, rash/hives).

Caution

- **Driving and Operating Heavy Machinery**
  Tiagabine may cause dizziness, drowsiness, trouble thinking, trouble with motor skills, or vision problems. It is recommended to not drive, operate heavy machinery, or perform any other task that may be dangerous if not fully alert until you know how this medication affects you.

- **Seizures in Patients Without Epilepsy**
  Post-marketing reports have shown that tiagabine use has been associated with new onset seizures and status epilepticus in patients without epilepsy. Additionally, safety and effectiveness of tiagabine have not been established for any indication other than as adjunctive therapy for partial seizures in adults and children 12 years and older. If you do experience a seizure while taking this medication for conditions other than experiencing seizures, please call your doctor promptly.

- **Suicidal Behavior and Ideation**
  Antiepileptic drugs (AEDs), including tiagabine, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. If you do experience new or worsening thoughts, please call your doctor immediately.

- **Withdrawal Seizures**
  As a rule, antiepilepsy drugs should not be abruptly discontinued because of the possibility of increasing seizure frequency. If for any reason you feel this drug needs to be stopped, please consult with your doctor. Do not stop taking this medication without talking to your doctor.

- **Skin Reactions**
  This medication may cause a rare, but severe rash in certain individuals. If you do notice a severe rash, or any other abnormal skin changes, please call your doctor promptly.

- **General Muscle Weakness**
  Moderately severe to generalized weakness has been reported after administration of tiagabine. The weakness resolved in all cases after a reduction in dose or discontinuation of tiagabine.

Warning
Seizures in Patients Without Epilepsy
Post-marketing reports have shown that tiagabine use has been associated with new onset seizures and status epilepticus in patients without epilepsy. Dose may be an important predisposing factor in the development of seizures, although seizures have been reported in patients taking daily doses of tiagabine as low as 4mg/day. In most cases, patients were using concomitant medications (antidepressants, antipsychotics, stimulants, narcotics) that are thought to lower the seizure threshold. Some seizures occurred near the time of a dose increase, even after periods of prior stable dosing.

The tiagabine dosing recommendations in current labeling for treatment of epilepsy were based on use in patients with partial seizures 12 years of age and older, most of whom were taking enzyme-inducing antiepileptic drugs (AEDs; e.g., carbamazepine, phenytoin, primidone and phenobarbital) which lower plasma levels of tiagabine by inducing its metabolism. Use of tiagabine without enzyme-inducing antiepileptic drugs results in blood levels about twice those attained in the studies on which current dosing recommendations are based.
Safety and effectiveness of tiagabine have not been established for any indication other than as adjunctive therapy for partial seizures in adults and children 12 years and older.

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In nonepileptic patients who develop seizures while on tiagabine treatment, tiagabine should be discontinued and patients should be evaluated for an underlying seizure disorder. Seizures and status epilepticus are known to occur with tiagabine overdosage.

Suicidal Behavior and Ideation

Antiepileptic drugs (AEDs), including tiagabine, 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. 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. 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 tiagabine 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 Seizures

As a rule, antiepilepsy drugs should not be abruptly discontinued because of the possibility of increasing seizure frequency. In a placebo-controlled, double-blind, dose-response study designed, in part, to investigate the capacity of tiagabine to induce withdrawal seizures, study drug was tapered over a 4-week period after 16 weeks of treatment. Patients' seizure frequency during this 4-week withdrawal period was compared to their baseline seizure frequency (before study drug). For each partial seizure type, for all partial seizure types combined, and for secondarily generalized tonic-clonic seizures, more patients experienced increases in their seizure frequencies during the withdrawal period in the three tiagabine groups than in the placebo group. The increase in seizure frequency was not affected by dose. Tiagabine should be withdrawn gradually to minimize the potential of increased seizure frequency, unless safety concerns require a more rapid withdrawal.

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

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Medication: Gabitril – (tiagabine)

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 _____