Ztalmy one™ Enrollment Form

FAX: 844-ZTALMY-F (844-982-5693)
PHONE: 844-ZTALMY-1 (844-982-5691) | Monday–Friday, 8 AM–8 PM ET

Instructions: Prescribers should fax the completed form along with copies of medical and pharmacy benefit cards (front and back) to ZTALMY One (844-982-5693). Attach clinical notes, including documentation of the patient's diagnosis if available, as well as a completed Letter of Medical Necessity (LMN) with the Enrollment Form. A sample LMN is available at ZTALMYhcp.com.

This form serves as a prescription for ZTALMY® (ganaxolone) oral suspension CV (see Section 4) and offers the patient or parent/guardian enrollment and participation in ZTALMY One, a Marinus patient support program offering access, affordability, and prescription drug support for caregivers and patients.

Prescribers: Complete Sections 1-4
Patient or Parent/Guardian: Complete Sections 5-7

Section 1: Patient Information

First Name: _____ Last Name: _____

Address: _____ City: _____ State: _____ ZIP: _____

Date of Birth: _____ Patient Sex: ☐ Male ☐ Female

Parent/Legal Guardian Name: _____

Phone #: _____ Email: _____

Instruct patient or parent/guardian to identify communication preferences in Section 5 on Page 4.

Section 2: Insurance Information (Provide copies of front and back of medical and pharmacy insurance cards and submit with this form)

☐ Check if patient does not have insurance

Primary Insurance Company: _____

Policy Holder: _____

Relationship to Patient: _____

Policy ID #: _____

Group #: _____

Phone #: _____

Prescription Drug Insurer: _____

Group #: _____ ID #: _____

Rx BIN #: _____ PCN #: _____

Phone #: _____

Secondary Insurance Company: _____

Policy Holder: _____

Relationship to Patient: _____

Policy ID #: _____

Group #: _____

Phone #: _____

Prescription Drug Insurer: _____

Group #: _____ ID #: _____

Rx BIN #: _____ PCN #: _____

Phone #: _____

MARINUS

Patient Name: _____ Patient Address: _____

Section 3: Prescriber Information

First Name: _____ Last Name: _____

Specialty: _____

Institution/Clinic/Office Name: _____

Address: _____ City: _____ State: _____ ZIP: _____

Phone #: _____ Fax: _____

NPI #: _____ State License #: _____

DEA #: _____

Office Contact Name: _____

Phone #: _____ Fax #: _____

Email: _____ Preferred Method of Contact: ☐ Phone ☐ Email

Section 4: Statement of Medical Necessity and Prescription

Diagnosis: ICD-10 G40.42 Cyclin-dependent kinase-like 5 deficiency disorder ☐ Yes ☐ No

Genetic testing completed to confirm diagnosis (attach test results if available): ☐ Yes ☐ No

Secondary diagnosis (*include ICD-10 codes if available*): _____

_____

Other diagnostic tests completed (eg, MRI, EEG, CT): _____

_____

Age of seizure onset: _____

Current frequency of major motor seizures (please provide number of total known/estimated events per month): _____

*Includes bilateral tonic, generalized tonic-clonic, atonic/drop, bilateral clonic, and focal to bilateral tonic-clonic.

Seizure treatments (please list or attach):

Current	Discontinued
☐ Clobazam	☐ Clobazam
☐ Levetiracetam	☐ Levetiracetam
☐ Steroids	☐ Steroids
☐ Valproate	☐ Valproate
☐ Vigabatrin	☐ Vigabatrin
☐ Other: _____	☐ Other: _____
☐ Other: _____	☐ Other: _____
☐ Other: _____	☐ Other: _____

Known allergies: _____

Additional interventions (eg, ketogenic diet): _____

Comorbidities (check all that apply or include clinical notes):

☐ Fine motor delay ☐ Gross motor delay ☐ Movement disorders

☐ Autonomic dysfunction ☐ GI disorders ☐ Generalized hypotonia

☐ Neurologic disorders ☐ Cortical visual impairment

☐ Intellectual disability ☐ Receptive and expressive communication

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Patient Name: _____ Patient Address: _____

ZTALMY® CV Prescription

Titration Rx

ZTALMY (ganaxolone) 50 mg/mL oral suspension, CV (110mL/bottle)

Quantity (mL): _____ Days' Supply: _____ Patient's Weight (kg): _____ No Refills

Titration Instructions (check one):

☐ Titrate per recommended schedule at right

☐ Titrate per instructions provided below

Days	Standard Dosage		Severe Hepatic Impairment*	
	Patients ≤28 kg	Patients >28 kg	Patients ≤28 kg	Patients >28 kg
Titration Week 1: Days 1-7	6 mg/kg TID (18 mg/kg/day)	150 mg TID (450 mg/day)	2 mg/kg TID (6 mg/kg/day)	50 mg TID (150 mg/day)
Titration Week 2: Days 8-14	11 mg/kg TID (33 mg/kg/day)	300 mg TID (900 mg/day)	3.66 mg/kg TID (11 mg/kg/day)	100 mg TID (300 mg/day)
Titration Week 3: Days 15-21	16 mg/kg TID (48 mg/kg/day)	450 mg TID (1350 mg/day)	5.33 mg/kg TID (16 mg/kg/day)	150 mg TID (450 mg/day)
Maintenance: Day 22 + ongoing	21 mg/kg TID (63 mg/kg/day)	600 mg TID (1800 mg/day)	7 mg/kg TID (21 mg/kg/day)	200 mg TID (600 mg/day)

**Dosage adjustments are required for patients with severe hepatic impairment (Child-Pugh class C). No dosage adjustments are necessary in patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment.*

Sig: _____

_____

_____

Maintenance Rx

ZTALMY (ganaxolone) 50 mg/mL oral suspension, CV (110ml/bottle)

Quantity (mL): _____ Days' Supply: _____ Patient's Weight (kg): _____

Refills (limit 5): _____ Sig: _____

_____

_____

Prescriber Certification

I certify that ZTALMY is medically necessary for this patient and that I have reviewed this therapy with the parent/guardian and will be monitoring the patient's treatment. I verify that the patient and the healthcare provider information on the enrollment form was completed by me or at my direction and that the information contained therein is complete and accurate to the best of my knowledge. I understand that I must comply with my practicing state's specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to me by the dispensing pharmacy. I authorize the designated specialty pharmacy and other designated pharmacy operators to perform a preliminary assessment of benefit verification for this patient and furnish information requested by the patient's insurer that is available on this form. I understand that insurance verification is ultimately the responsibility of the provider and third-party reimbursement is affected by a variety of factors. I understand that while the specialty pharmacy tries to provide accurate information, neither the designated specialty pharmacy nor Marinus make any representations or warranties as to the accuracy of the information provided. I understand that representatives from the specialty pharmacy may contact me or my patient for additional information relating to this enrollment form.

I certify that neither I nor my affiliated practice or facility will bill or seek reimbursement for any ZTALMY provided at no charge through a ZTALMY One prescription support program (PAP or Bridge Program) from the patient, or any third-party payer or insurer (including any federal healthcare programs). I also certify that I have obtained all necessary consents and HIPAA Authorization from the patient or parent/guardian for the designated specialty pharmacy to perform these services on his/her behalf (see HIPAA Authorization in Section 7 on page 5).

Prescriber signature required for consent and to validate prescriptions. Prescriber attests that this is his/her signature.

_____ _____

Prescriber Name (print) **Date**

_____

Prescriber Signature (no stamps) ☐ Dispense as written ☐ Substitution permitted

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Patient Name: _____ Patient Address: _____

Section 5: Communication Preferences (to be completed by parent/guardian)

Patient Name: _____

Parent/Legal Guardian Name: _____

Preferred Phone #: _____ ☐ Check if mobile

Best time to call: _____ OK to leave a message? ☐ Yes ☐ No

OK to text for prescription refills and patient support? ☐ Yes ☐ No

Preferred language: _____ Email: _____

Section 6: ZTALMY One™ Prescription Drug Support Programs

Copay Savings Program

I am requesting that Marinus' authorized agent(s) check my or my child's eligibility for participation in the ZTALMY One Copay Savings Program which helps reduce out of pocket costs for eligible commercially insured patients prescribed ZTALMY® (ganaxolone) CV. Patients enrolled in or eligible for any federal or state healthcare programs including but not limited to Medicare, Medicaid, Veterans Affairs (VA), Tricare or the Department of Defense (DOD) programs are not eligible for participation.

Patient Assistance Programs

I am requesting that Marinus' authorized agent(s) check my or my child's eligibility for participation in ZTALMY One prescription drug support programs offered for:

Eligible patients taking ZTALMY who experience a temporary gap or delay in prescription drug insurance and receive a limited supply of ZTALMY during the prescription drug insurance gap/delay.

Eligible uninsured or underinsured patients prescribed ZTALMY who meet program-specific financial need criteria and other eligibility requirements. Underinsured patients with commercial or government insurance may be eligible for program participation.

ZTALMY One prescription drug support programs are subject to eligibility requirements and terms and conditions. Marinus may change, amend, or discontinue the ZTALMY One program and the prescription drug support programs at any time without notice.

Signature section is on Page 5.

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Patient Name: _____ Patient Address: _____

Section 7: HIPAA Authorization to Use and Disclose Protected Health Information (to be completed by parent/guardian)

I authorize my healthcare providers and health plans to disclose, transmit, or use personally identifiable information and medical information about my child, including but not limited to information about his/her medical condition, treatment with ZTALMY® (ganaxolone) CV, and health insurance coverage, and my and my child's demographic information (collectively, "Protected Health Information"). I authorize my healthcare providers and health plans to disclose my child's Protected Health Information to Marinus' authorized agents. Marinus' authorized agents include but are not limited to specialty pharmacy partners, as well as third parties working with specialty pharmacy partners, for the purposes described in this HIPAA Authorization. I understand that Marinus will not receive any of my child's Protected Health Information.

I authorize my healthcare providers and health plans to disclose to Marinus' authorized agents my information and my child's Protected Health Information to receive the following services:

- To investigate my child's health insurance coverage benefits.
- To determine if my child is eligible to participate in ZTALMY One™ prescription drug support programs referenced on page 4 to help with the cost of ZTALMY.
- To refer my child to other programs or alternate sources that may be able to help with the costs of ZTALMY.
- To contact me about refilling my child's ZTALMY prescription by email, phone call, or text.
- To contact me about program support services related to ZTALMY One.
- To provide me with marketing materials about ZTALMY and educational materials about cyclin-dependent kinase-like 5 deficiency disorder (CDD).

☐ Opt out of receiving marketing materials about ZTALMY ☐ Opt out of receiving educational materials about CDD

I understand that this HIPAA Authorization is voluntary and that my child's medical treatment, my ability to seek payment for this treatment, or my or my child's enrollment in or eligibility for insurance coverage will not be affected by whether I sign this HIPAA Authorization. However, I understand that if I decline to sign this HIPAA Authorization, I may not be able to participate in the full services offered by the ZTALMY One Program. I understand that once disclosed to Marinus' authorized agents, my information and my child's Protected Health Information disclosed under this HIPAA Authorization may be further disclosed by the recipients and may no longer be protected by federal privacy law.

I understand that I may withdraw this HIPAA Authorization at any time by emailing a request to: privacy@marinuspharma.com, except to the extent that action already has been taken in reliance on this HIPAA Authorization.

I am entitled to a copy of this HIPAA Authorization, which will expire ten (10) years from the date it is signed by me (unless earlier termination is required by applicable state law).

_____

Name of Patient (Print)

_____

Name of Parent/Guardian (Print)

_____

Signature of Parent/Guardian

_____ _____

Relationship to Patient **Date**

MARINUS