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.

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: _____

Section 2: Consent and Direction to Release and Process Health Information

I understand that by signing below, I am indicating that I have read and understand the Consent and Direction to Release and Process Health Information (page 4 and 5) and I am legally authorized to consent, and that I am providing my consent (as the patient or the patient's legal representative for Immedica) to use and share my Health Information for the purposes described within the Consent and Direction to Release and Process Health Information.

_____ _____
Patient (or Legal Representative) Signature Date Signed

_____ _____
Patient Name (printed) Legal Representative Name (if applicable & printed)

_____ _____
Mobile Phone* Home Phone

*By providing my mobile number, I am agreeing to receive calls and texts related to Immedica's patient support services program, which I can stop at any time.

Section 3: 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 #: _____

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Patient Name: _____ Patient Address: _____

Section 3: Prescriber Information

First Name: _____ Last Name: _____

Speciality: _____

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: Diagnosis and Prescription

Diagnosis: Seizures associated with

☐ CDKL5 Deficiency Disorder (G40.42)

☐ Other, ICD-10 _____

Age of seizure onset: _____

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):

☐ 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

Patient Name: _____ Patient Address: _____

ZTALMY® Prescription

Titration Rx

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

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

Titration Instructions (check one):

- ☐ Titrate per Standard Dosage—see table at right
- ☐ Titrate per Severe Hepatic Impairment dosage—see table at right
- ☐ Titrate per Instructions provided below

Days	Standard Dosage		Severe Hepatic Impairment*	
	Patients ≤28kg	Patients >28kg	Patients ≤28kg	Patients >28kg
Titration Week 1: Days 1-7	2 mg/kg three times daily (6 mg/kg/day)	50 mg three times daily (150 mg)	0.66 mg/kg three times daily (2 mg/kg/day)	17 mg three times daily (50 mg)
Titration Week 2: Days 8-14	4 mg/kg three times daily (12 mg/kg/day)	100 mg three times daily (300 mg)	1.33 mg/kg three times daily (4 mg/kg/day)	33 mg three times daily (100 mg)
Titration Week 3: Days 15-21	8 mg/kg three times daily (24 mg/kg/day)	200 mg three times daily (600 mg)	2.66 mg/kg three times daily (8 mg/kg/day)	67 mg three times daily (200 mg)
Titration Week 4: Days 22-28	14 mg/kg three times daily (42 mg/kg/day)	400 mg three times daily (1,200 mg)	4.66 mg/kg three times daily (14 mg/kg/day)	133 mg three times daily (400 mg)
Maintenance: Day 29 and thereafter	21 mg/kg three times daily (63 mg/kg/day)	600 mg three times daily (1,800 mg)	7 mg/kg three times daily (21 mg/kg/day)	200 mg three times daily (600 mg)

*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. Total daily dose is an approximation.

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: _____

_____

_____

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Patient Name: _____ Patient Address: _____

State requirements: the prescriber is to comply with state-specific prescription requirements such as e-prescribing, prescription form, fax language, etc. Noncompliance with state-specific requirements could result in outreach to the prescriber.

Signature below indicates prescription authorization and prescriber certification.

Prescriber signature* Written or e-signature only; stamps not acceptable.

_____ Date: ____ /____ /_____

Dispense as written (MM/DD/YYYY)

Prescriber Certification

I certify that (1) the above medicine is medically necessary for this patient, (2) I have reviewed this therapy with the patient and/or parent/guardian and will be monitoring the patient's treatment, (3) the information on the enrollment form was completed by me or at my direction and (4) the information contained therein is complete and accurate to the best of my knowledge. Further, I also certify that I (1) am disclosing the information on this form for the treatment purposes of the patient, (2) have discussed this program with the patient or parent/guardian, (3) am acting at their direction and (4) have obtained all necessary consents from the patient or parent/guardian to disclose personal information to the patient's insurance providers and to Immedica Pharma US Inc. and its affiliates and their respective employees, agents, service providers, business partners and designees, including any designated specialty pharmacy ("Immedica"), for the purposes of administering a patient support services program (including conducting a benefit assessment and to furnish it as necessary to support patient access), and providing treatment and access education and non-medical logistical support on the patient's behalf. I understand that Immedica may contact me or my patient for additional information relating to this enrollment form.

I agree that any program, service or medicine provided as a result of completing this form is solely for the benefit of the specified patient and does not constitute a direct or indirect inducement or reward to prescribe, use or recommend an Immedica service, program or medicine. Additionally, I acknowledge that Immedica does not represent or guarantee reimbursement or coverage for any medicine or related services and that the patient and their healthcare provider are responsible for insurance and benefit verification and completing any documentation seeking reimbursement or coverage. Further, neither I nor my affiliated practice or facility will bill or seek reimbursement for any such patient support program or service, including any medicine provided free of charge through a bridge or patient assistance program, from the patient or any third-party payer or insurer (including any federal healthcare programs).

I understand that I must comply with my practicing state's specific prescription requirements such as e-prescribing mandates, state-specific prescription forms, required fax language, etc. Non-compliance with state-specific requirements could result in outreach from the dispensing pharmacy.

Consent and Direction to Release and Process Health Information

I hereby direct my health care providers—including my doctors and their staff, health care plan and insurance company, pharmacies, laboratories, and similar health care entities, and/or their contractors (collectively "Health Care Providers"), to disclose my Health Information, as described below, to Immedica Pharma US Inc. and its affiliates, agents, service providers (including Veeva), business partners and designees, (collectively and individually, "Immedica") and to use my Health Information as described below. If I signed this form as a legal representative, I understand that references to "my Health Information" or similar phrases, refer to the Health Information of the individual whose interests I am representing.

My Health Information includes my protected health information, my contact information, and any other records that pertain to my medical care, treatment, prescriptions, history, and prognosis as well as claim forms, Explanation of Benefits, enrollment information, premium information or other benefits information or documents—to/from insurance companies, self-insured plans, TPA's, claims administrators, Plan Sponsors, Plan Administrators, utilization review companies or other third-party payers involved with evaluating, adjusting, processing or paying my claim(s) for insurance benefits, whether pre-service or post-service in nature related to or potentially relevant for the Program as defined below.

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Patient Name: _____ Patient Address: _____

Consent and Direction to Release and Process Health Information (continued)

I understand and agree that Immedica and my specialty pharmacies and designated care centers, will process, use, and disclose my Health Information—including any inferences that may be drawn from my Health Information, and which may be considered to be "Sensitive Data" and/or "Consumer Health Data" under the laws of some states—for purposes of supporting my participation in Immedica's patient support services program ("Program"). The Program will (i) assist me with applying for prior authorizations and reimbursements from my insurance plan; (ii) assist with navigating any appeal, grievance, and/or independent review of a denial of insurance benefits and/or coverage; (iii) provide me with patient support services and educational materials about the above medicine or any other Immedica-affiliated patient support services and activities related to my condition or treatment (for example, co-pay card programs, bridge or patient assistance programs, reimbursement assistance programs, drug coverage verification, patient access liaison services, adherence program and disease management support); (iv) improve, develop, and evaluate Immedica's products, services, materials and programs that are related to my condition or treatment; and (v) facilitate communication between my Health Care Providers, Immedica, myself and/or my representative. I understand that as part of the Program, Immedica will communicate directly with my healthcare providers and health plans regarding my treatment/therapy and benefit coverage and will contact me with patient support services, educational materials, or other Program communications.

I understand that Immedica will not sell my Health Information to third parties, but may disclose my Health Information to Immedica's agents, service providers, and business partners for Immedica's business purposes related to the Program. I also understand that my Health Care Providers and Immedica's servicers providers, including specialty pharmacies, may receive payment from Immedica for providing services including the use and disclosure of my Health Information to Immedica. I understand that Immedica may use my Health Information to contact me by mail, email, and if I provided my number, by telephone or text, for the above purposes.

I understand that I may terminate this direction and consent to my Health Care Providers to release my Health Information and/or revoke my consent for the continued collection and processing of my Sensitive Data/Consumer Health Data, as defined under state law, in connection with the Program, by contacting Immedica via privacy@immedica.com. I understand that my termination/revocation could mean that I will not get the full benefit of the Program. I understand that my termination/revocation will not have a retroactive effect on any Health Information collection or processing activities which Immedica took before it received my termination/revocation, and that my termination/revocation will mean that I will not have access to support services from the Program.

I understand that I may have additional rights in certain states, such as the right to access a copy of the Health Information Immedica has collected about me and the right to request deletion of this data. I understand that Immedica will honor these requests where reasonably possible, but that it will maintain my Sensitive Data despite my deletion request where it is used for solely internal purposes reasonably aligned with my expectations, or where Immedica must maintain it to prosecute or defend their legal rights or to comply with legal or regulatory obligations. I understand the information disclosed pursuant to this Consent and Direction to Release may be used or disclosed by the recipient as stated herein, but that it will no longer be protected by the federal HIPAA privacy rules, but that laws and regulations under applicable state law will still apply. I understand I can access Immedica's Privacy Statement and Consumer Health Data Statement at ImmedicaUS.com, which also includes a description of my privacy rights.

I request that any Health Information disclosed by my Health Care Providers pursuant to this request be transmitted to Immedica's secure portal (including a portal operated by Immedica's affiliates, agents, or service providers), or if a portal is not available, in a manner providing reasonable safeguards, without need for further written agreement. Further, this disclosure request is made pursuant to my right under HIPAA to access my Health Information and direct it to third parties of my choosing.

Marketed by:
Immedica Pharma US Inc., Chicago, IL 60642