

GETTING YOUR PATIENTS STARTED ON ZTALMY®

Lina is living with CDD.

IMPORTANT SAFETY INFORMATION AND INDICATION

INDICATION AND USAGE

ZTALMY is indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years and older.

Please see additional **Important Safety Information** throughout and consult the full **Prescribing Information**.

Ztalmy® (ganaxolone) oral suspension | 50 mg/mL

Support for getting your patients *started*

ZTALMY® (ganaxolone) CV is the first treatment indicated specifically for seizures associated with CDKL5 deficiency disorder in patients 2 years and older.[1] When you prescribe ZTALMY, know there is support to help your patients get access to the treatment they need.

Ztalmy *one*™

ZTALMY One is a comprehensive support program for you and your patients. We provide resources, support, and education to help your patients throughout treatment.

ZTALMY One* support includes:



Facilitating access to treatment



Offering prescription support to help with affordability



Providing ongoing prescription support and education

**Eligibility Terms and Conditions apply.*

Here for you at every step

From getting your patients started to answering questions throughout the treatment journey, ZTALMY One is here for you at every step. Your ZTALMY One support team includes Patient Care Coordinators† (available Monday through Friday, 8 AM to 8 PM ET) and pharmacists (available 24/7).

Connect with Ztalmy *one*™ **1-844-ZTALMY-1**
(1-844-982-5691)

†ZTALMY One Patient Care Coordinators do not provide medical advice or individual patient care.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Somnolence and Sedation: ZTALMY can cause somnolence and sedation. In a clinical study somnolence and sedation appeared early during treatment and were generally dose related. Other CNS depressants, including opioids, antidepressants, and alcohol, could potentiate these effects. Monitor patients for these effects and advise them not to drive or operate machinery until they have gained sufficient experience on ZTALMY to gauge whether it adversely affects their ability to drive or operate machinery.

Please see additional **Important Safety Information** throughout and consult the full **Prescribing Information**.

Ready to *prescribe* ZTALMY®? Start here

ZTALMY is supplied through Orsini Specialty Pharmacy by ZTALMY One™. Follow these steps to prescribe ZTALMY and enroll your patients in ZTALMY One.

- Fill out the **ZTALMY One Enrollment Form**.
- Have your patient's caregiver sign the enrollment form to receive additional resources from ZTALMY One throughout treatment. Your patient's caregiver can sign the form electronically.
- Include a **Letter of Medical Necessity** (LMN) and any clinical notes, including documentation of the patient's diagnosis if available, with the enrollment form to support the prior authorization process. **The Clinical Documentation Reference** can help you capture relevant clinical information for the LMN.
- Fax the ZTALMY One Enrollment Form and supporting documentation to 1-844-ZTALMY-F (1-844-982-5693).

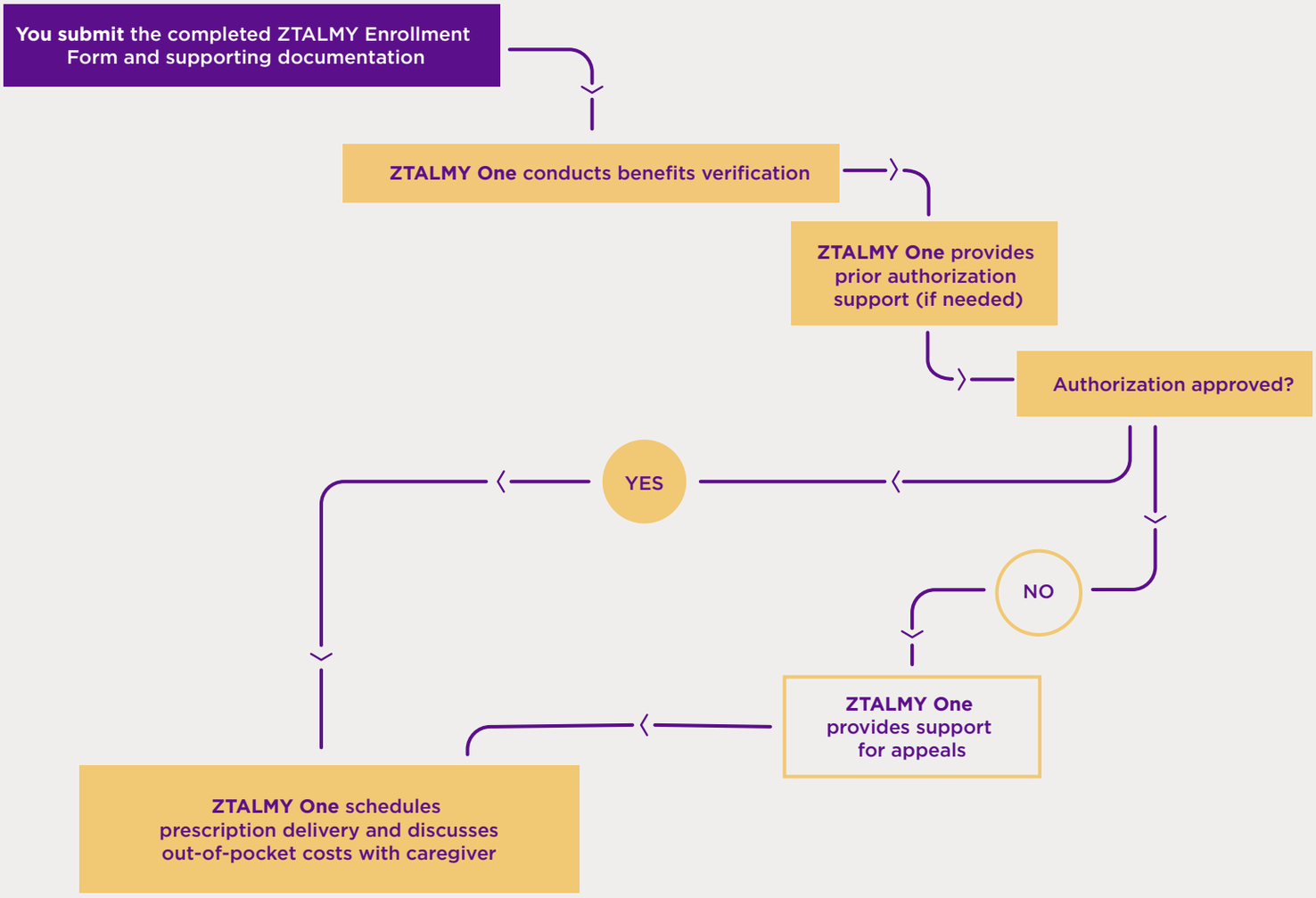
What's next? After you submit the enrollment form and supporting documentation, ZTALMY One will contact your office confirming that we have everything we need to begin prior authorization.

For copies of the ZTALMY One Enrollment Form and to see a sample LMN, visit **ztalmyhcp.com/prescribe**

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ZTALMY One™ helps facilitate *access* to treatment

After you prescribe ZTALMY® (ganaxolone) CV, ZTALMY One will provide support throughout the access process



Benefits verification

ZTALMY One will investigate your patient's benefits, including specific coverage and payer requirements. If there are any issues, such as patient eligibility, a Patient Care Coordinator will reach out to you within 2 business days to explain what is needed.

Prior authorization support

ZTALMY One will help with prior authorization. A Patient Care Coordinator will create a patient key in CoverMyMeds® and upload all relevant documentation. We will contact you to fill in any outstanding information for the patient key. Be sure to sign and submit the prior authorization in CoverMyMeds® so that it can be processed.

If a prior authorization does not get approved, ZTALMY One will also investigate the reasons for denial or rejection, and provide support for an appeal, including an appeals template if needed.

Your patient's prescription delivery

Once your patient's coverage has been determined, ZTALMY One will contact the caregiver to coordinate delivery and discuss any out-of-pocket costs. Please remind caregivers that they must answer or return this call to receive their prescription.

ZTALMY One™ offers *support* throughout treatment

Helping to make treatment more affordable



ZTALMY One Copay Savings Program

The ZTALMY One Copay Savings Program helps commercially insured eligible patients pay as low as zero dollars per fill for a ZTALMY® prescription.*

*Eligible patients may pay as low as $0 per fill for a ZTALMY prescription for a maximum 30-day supply per fill, subject to an annual maximum. State and federal health care program beneficiaries not eligible even if they elect to be processed as an uninsured (cash-paying) patient. The savings program is not health insurance. Immedica Pharma US Inc. reserves the right to rescind, revoke or amend this offer without notice. See full terms and conditions. For questions, please call ZTALMY One (1-844-982-5691).



Prescription Support Programs

If your patient has no insurance, limited insurance, or a gap or delay in coverage, our prescription support programs may be able to help with the cost of your patient's prescription.

Eligibility Terms and Conditions apply.

Providing ongoing support for your patients

Caregivers will receive monthly check-in calls from ZTALMY One to discuss:

- Weight changes that may affect their loved one's dosage
- Upcoming refills
- The next delivery of ZTALMY to the patient's home



See the Dosing and Titration Reference for information on calculating your patient's dose

Program Eligibility and Terms and Conditions
The copay savings program requires a valid prescription for ZTALMY (ganaxolone) oral suspension, CV consistent with the Prescribing Information. Patient must have commercial insurance. Offer is not valid for cash-paying patients. Patient must reside in the U.S. or U.S. Territory. Patients are responsible for as low as a zero-dollar copayment for a ZTALMY prescription for a maximum 30-day supply per fill. The value of the copay savings program offer is limited to an annual maximum per calendar year. For maximum annual benefit limit information, please contact ZTALMY One™ (1-844-982-5691). Patients are not eligible to use this offer if they are eligible for or enrolled in a state or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veteran Affairs health care or a state prescription drug assistance program. Patients are responsible for reporting use of the copay savings program to any commercial insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled using the copay savings program, as may be required. Patients should not use the copay savings program if their insurer or health plan prohibits use of manufacturer copay programs. Offer not valid where prohibited by law. Copay Savings Program accepted only by the ZTALMY One designated specialty pharmacy. If patient's insurance changes, the pharmacy must be notified immediately. Based on patient's insurance change, patient may no longer be able to participate in the copay savings program. Offer is not health insurance. Offer good only in the U.S. Offer is limited to one per person during this offering period and is not transferable. Offer is not conditioned on any past, present, or future purchase, including refills. Immedica Pharma US Inc. reserves the right to rescind, revoke or amend this offer and program eligibility requirements at any time without notice.

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- **Suicidal Behavior and Ideation:** Antiepileptic drugs (AEDs), including ZTALMY, increase the risk of suicidal thoughts or behavior. Monitor patients taking ZTALMY for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior. Advise patients, caregivers, and their families to be alert for these behavioral changes and report behaviors of concern immediately to healthcare providers. When considering ZTALMY, or any other AED, balance the risk of suicidal thoughts or behaviors with the risk of untreated illness. If these symptoms emerge during treatment, consider whether it may be related to the AED or the underlying illness.
- **Withdrawal of Antiepileptic Drugs:** As with most AEDs, withdraw ZTALMY gradually to minimize the risk of increased seizure frequency and status epilepticus. If withdrawal is needed because of a serious adverse event, rapid discontinuation can be considered.

ADVERSE REACTIONS

The most common adverse reactions (incidence of at least 5% and at least twice the rate of placebo) were somnolence (38%), pyrexia (18%), salivary hypersecretion (6%), and seasonal allergy (6%).

DRUG INTERACTIONS

Cytochrome P450 inducers will decrease ganaxolone exposure. Avoid concomitant use with strong or moderate CYP3A4 inducers; if unavoidable, consider a dosage increase of ZTALMY, but do not exceed the maximum recommended dosage.

UGT inhibitors may increase ganaxolone exposure. Consider a reduction of ZTALMY maintenance dose when initiating UGT inhibitors.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Use caution when ZTALMY is administered to pregnant women as there are no adequate data on the developmental risk associated with use in pregnant women. In animal studies, developmental adverse effects were observed following exposure during organogenesis or throughout gestation and lactation.
- **Lactation:** ZTALMY is excreted in human milk at concentrations resulting in a dose to the breastfed infant of less than 1% maternal dose. The effects of ZTALMY on milk production and the breastfed infant are unknown.
- **Hepatic Impairment:** Administration of ZTALMY in patients with severe hepatic impairment (Child-Pugh class C) results in elevated ganaxolone plasma concentrations. Therefore, dosage adjustment in these patients during titration and maintenance is required. No dosage adjustment is necessary in patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment.

DRUG ABUSE AND DEPENDENCE

ZTALMY contains ganaxolone, a Schedule V controlled substance (CV). Advise patients of the potential for abuse and dependence. It is recommended that ZTALMY be tapered according to the dosage recommendations unless symptoms warrant immediate discontinuation.

Please see full **Prescribing Information**.

Reference: Ztalmy. Package insert. Immedica Pharma US Inc.

Immedica pharma

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