This sample letter of medical necessity may be customized by your office and submitted to insurers as part of the prior authorization or pre-determination process. If you have any questions about this template letter, please contact ZTALMY One™ at 1-844-ZTALMY-1 (844-982-5691), Monday through Friday, 8am to 8pm ET.

[Practice Letterhead]

[Date]

[Name of Medical Director]

[Name of Insurer]

[Address]

[City, State, Zip Code]

Re: [Patient’s Name]

 [Patient ID Number]

Diagnosis: ICD-10 G40.42 Cyclin-dependent kinase-like 5 deficiency disorder

I am writing to provide additional information regarding the medical necessity of treating one of your members, [Patient Name], with ZTALMY® (ganaxolone) oral suspension, CV. On March 18, 2022, the U.S. Food and Drug Administration (FDA) approved ZTALMY® (ganaxolone) for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) Deficiency Disorder (CDD) in patients 2 years of age and older. ZTALMY contains ganaxolone, a Schedule V controlled substance. This letter provides information about my patient’s medical history and my rationale for prescribing ZTALMY.

**Disease Overview**

CDD is a serious and rare genetic disorder that is caused by a mutation of the cyclin-dependent kinase-like 5 (*CDKL5*) gene located on the X chromosome. The incidence is approximately 1:40,000 live births and predominantly affects females. Genetic testing is available to determine if a patient has a mutation in the *CDKL5* gene. CDD is characterized by early-onset, frequent, difficult-to-control seizures and severe neuro-developmental impairment on cognitive, motor, speech and visual function.

**Diagnosis**

Insert details and/or attach supporting documentation including:

* Age at seizure onset
* Age at diagnosis
* Current patient weight
* Confirmed genetic test indicating variant in *CDKL5* gene and date completed
* Other labs or diagnostic tests completed (MRI, EEG, CT)

**Clinical Course of CDD**

Insert details and/or attach supporting documentation including:

* Seizure frequency and types
* Developmental delays
* Other clinical features such as gastrointestinal disturbances, visual impairment, muscle weakness or sleep disturbances
* Impact on quality of life for patient and family

**Disease Management and Treatment**

Insert details and/or attach supporting documentation including:

* Previous and current therapies, duration of treatment, and rationale for discontinuation or changing therapies
* Other interventions such as diet, occupational therapy, surgical interventions, etc.
* Any other relevant documentation about how CDD is treated or managed in this patient

Reducing the frequency of seizures is one of the primary goals of treatment. It is my opinion that ZTALMY® is an appropriate treatment for my patient. The clinical trial was randomized, double blind, placebo controlled trial of 101 patients, ages 2-19, with uncontrolled seizures associated with CDD. ZTALMY significantly reduced the frequency of CDD-associated seizures by 31% compared to 7% for placebo. Most common adverse reactions included somnolence, pyrexia, salivary hypersecretion, and seasonal allergy. ZTALMY is administered orally 3 times a day with food and is titrated, as tolerated, over 3 weeks to reach the maximum recommended daily dose.

Based on my medical evaluation and diagnosis of my patient’s condition, and the efficacy and safety demonstrated in the clinical trial, it is my professional opinion that [Patient Name] should receive treatment with ZTALMY.

I trust that this information is helpful to understand why I have prescribed treatment with ZTALMY. If you require any additional information, please contact me at [phone number and/or email].

Sincerely,

Name

Title

Address

City, State Zip

Phone

Email

Enclosures [attach as appropriate]

[Prescribing Information]

[Patient medical records, clinical notes and laboratory results]

[Publications]