Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

Ganaxolone (Ztalmy)

Notes:

• Quantity Limits: Yes

Initiation (new start) criteria: Non-formulary **ganaxolone (Ztalmy)** will be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- Prescribed by a neurologist
- Patient is 2 years of age or older
- Prescribed for seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder
- Patient has failed an adequate trial of, or patient has an allergy or intolerance to at least 4 other antiepileptic medications
- Patient is currently treated with at least 1 other antiepileptic medication

<u>Criteria for new members entering Kaiser Permanente already taking the</u> <u>medication who have not been reviewed previously</u>: Non-formulary ganaxolone (Ztalmy) will be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- Patient is 2 years of age or older
- Prescribed for seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder
- Patient has failed an adequate trial of, or patient has an allergy or intolerance to at least 4 other antiepileptic medications
- Patient is currently treated with at least 1 other antiepileptic medication

<u>Continued use criteria for patients previously approved per the above criteria who</u> <u>are currently stable on the medication</u>: Non-formulary ganaxolone (Ztalmy) will continue to be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- Continues to be prescribed by a neurologist
- Patient has experienced sustained improvement in seizure control (frequency and/or severity) since starting medication, as documented by neurologist

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