SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Ztalmy® (ganaxolone)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Members weighing 28 kg or less		**Members weighing more than 28 kg**	
Days of Therapy	**Maximum Total Daily Dose**	**Days of Therapy**	**Maximum Total Daily Dose**
1 to 7	6 mg/kg 3 times daily **18 mg/kg/day**	1 to 7	150 mg 3 times daily **450 mg**
8 to 14	11 mg/kg 3 times daily **33 mg/kg/day**	8 to 14	300 mg 3 times daily **900 mg**
15 to 21	16 mg/kg 3 times daily **48 mg/kg/day**	15 to 21	450 mg 3 times daily **1350 mg**
22 and ongoing	21 mg/kg 3 times daily **63 mg/kg/day**	22 and ongoing	600 mg 3 times daily **1800 mg**

Quantity Limit: 10 bottles per 30 days

(Continued on next page)

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Medication must be prescribed by or in consultation with a neurologist
- ❑ Member must be 2 years of age or older
- ❑ Member has a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) confirmed with genetic testing **(must submit documentation)**
- ❑ Member must be refractory to at least **TWO** antiepileptic drugs (e.g., clobazam, levetiracetam, topiramate, valproate) **(verified by chart notes or pharmacy paid claims)**
- ❑ Member will be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, unusual changes in mood or behavior
- ❑ Member will avoid concomitant therapy with moderate or strong CYP450 inducers (e.g., carbamazepine, phenobarbital, phenytoin, omeprazole), or if concomitant therapy is unavoidable, dose adjustments will be considered

Reauthorization: 12 months. All criteria that apply must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Member must continue to meet initial authorization criteria
- ❑ Member has demonstrated a positive response to Ztalmy® therapy, defined as a decrease from baseline and stabilization of seizure frequency **(submit chart notes)**
- ❑ Member must be absent of unacceptable toxicity from therapy (e.g., somnolence, pyrexia, suicidal thoughts, or behavior)

Not all drugs may be covered under every Plan.

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*