SENTARA COMMUNITY PLAN (MEDICAID)

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 <u>1-800-750-9692</u>. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If information provided is not complete, correct, or legible, authorization may be delayed.

Drug Requested: Ztalmy® (ganaxolone)

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

| Member Name: | | | |
|---------------------------------|------------------------------------|--|--|
| Member Sentara #: | | | |
| Prescriber Name: | | | |
| | Date: | | |
| Office Contact Name: | | | |
| Phone Number: | | | |
| DEA OR NPI #: | | | |
| DRUG INFORMATION: Authorization | tion may be delayed if incomplete. | | |
| Drug Form/Strength: | | | |
| Dosing Schedule: | | | |
| Diagnosis: | ICD Code: | | |

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 |

<u>Ouantity Limit</u>: 10 bottles per 30 days

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: 12 months

- □ Medication must be prescribed by or in consultation with a neurologist geneticist, or physician who is specialized in the treatment of epileptic disorders
- □ 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)
- Documentation that seizures have been inadequately controlled by a trial of at least 2 antiepileptic drugs (e.g., clobazam, valproate, lamotrigine, levetiracetam, topiramate, felbamate, vigabatrin) or member has labeled contraindications to other antiepileptic drugs

<u>Reauthorization</u>: 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.

□ Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms (e.g., reduced seizure activity, frequency, and/or duration)

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria. *<u>Previous therapies will be verified through pharmacy paid claims or submitted chart notes.</u>*