

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 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: Vioice[®] (alpelisib)

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: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Quantity Limits:

- 50 mg granule packet = 1 packet per day
- 50 mg therapy pack = 1 tablet per day
- 125 mg therapy pack = 1 tablet per day
- 250 mg therapy pack = 56 tablets (1 box) per 28 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: 6 months

- Member is 2 years of age or older
- Requesting provider is an oncologist, having a specialty in treating patients with PIK3CA-Related Overgrowth Spectrum

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- Member has a diagnosis of PIK3CA-Related Overgrowth Spectrum, confirmed by **BOTH** of the following:
 - Documented evidence for a PIK3CA gene mutation
 - Member has at least one target lesion identified on imaging
- Member's condition is severe or life-threatening requiring systemic therapy (**documentation of severe clinical manifestations include Congenital Lipomatous Overgrowth, Vascular malformations, Epidermal nevi, Scoliosis/skeletal and spinal [CLOVES], Facial Infiltrating Lipomatosis [FIL], Klippel-Trenaunay Syndrome [KTS], Megalencephaly-Capillary Malformation Polymicrogyria [MCAP]**)
- Member's age and weight must meet **ONE** of the following:
 - Age 2-5 years: 50 mg (1 tablet or granule packet) per day
 - Age 6-17 years: 125 mg (1 tablet) per day
 - Age > 18 years: 250 mg therapy pack (2 tablets) per day

Reauthorization: 12 months. 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.

- Member is responding positively to therapy as evidenced by subsequent imaging scan with a reduction in sum of measurable lesion volume assessed across 1 to 3 target lesions (**radiological response defined as a $\geq 20\%$ reduction from baseline in the sum of target lesion volume**)
- Member is **NOT** experiencing any toxicity from therapy (e.g., severe cutaneous adverse reactions, severe hyperglycemia, severe lung toxicity)
- Member's age and weight continues to meet **ONE** of the following (**Provider please note: If request is for a dose increase, new dose must NOT exceed any of the following**):
 - Age 2-5 years: 50 mg (1 tablet or granule packet) per day
 - Age 6-17 years: 125 mg (1 tablet) per day
 - Age > 18 years: 250 mg therapy pack (2 tablets) per day

Medication being provided by Specialty Pharmacy – Proprium Rx

*****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.****