

alpelisib tablet (VIOICE)

Diagnoses Considered for Coverage:

- PIK3CA-Related Overgrowth Spectrum (PROS)

Coverage Criteria:

For diagnosis of PIK3CA-related overgrowth spectrum (PROS):

INITIAL AUTHORIZATION

- Severe PROS with presence of PIK3CA mutation, **and**
- Patient is at least 2 years old, **and**
- Patient has at least one target lesion identified on imaging, **and**
- Dose does not exceed FDA label maximum:
 - 2 to <18 yrs of age: 50 mg per day
 - 18 yrs of age or older: 250 mg per day

Coverage Duration: 6 months

REAUTHORIZATION

- Patient has positive clinical response (e.g. reduction in target lesion volume), **and**
- Dose does not exceed FDA label maximum:
 - 2 to <18 yrs of age: 50 mg per day
 - 18 yrs of age or older: 250 mg per day

Coverage Duration: one year

Coverage Duration: See coverage criteria.

Effective Date: 09/27/2023