

SPECIALTY GUIDELINE MANAGEMENT

VIJOICE (alpelisib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Vioice is indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

1. Initial requests: Documentation of test confirming presence of *PIK3CA* mutation and physician confirmed/documented diagnosis of PROS
2. Continuation requests: chart notes or medical records documenting a benefit from therapy (e.g., improvement in symptoms and/or target lesions)

III. CRITERIA FOR INITIAL APPROVAL

PIK3CA-Related Overgrowth Spectrum (PROS)

Authorization of 6 months may be granted for treatment of PROS when all of the following criteria are met:

1. The member is at least 2 years of age
2. The member has a *PIK3CA* mutation and documented/confirmed diagnosis of PROS
3. Patient has at least one target lesion identified on imaging
4. Patient's condition is severe or life threatening and treatment is deemed necessary as determined by the treating physician

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting continuation of therapy if there is no evidence of unacceptable toxicity/disease progression, or positive response to therapy is evidenced by at least a 20% reduction in the lesion or lesions the approval was based upon.

V. QUANTITY LIMIT

1. Vioice 50mg daily dose pack has a quantity limit of 1 tablet per day (1 dose pack per 28 days)
2. Vioice 125mg daily dose pack has a quantity limit of 1 tablet per day (1 dose pack per 28 days)
3. Vioice 250mg daily dose pack has a quantity limit of 2 tablets per day (1 dose pack per 28 days)

VI. REFERENCES

1. Vioice [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2022.