Effective Date: 11/01/2022
Reviewed: 06/2022, 07/2023, 06/2024, 10/2024 Scope: Medicaid

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
Vijoice 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. 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. Documentation that the member has a *PIK3CA* mutation and documented/confirmed diagnosis of PROS
3. Documentation that the member has at least one target lesion identified on imaging
4. Documentation that the member has severe or life-threatening manifestations of disease and requires systemic therapy as determined by the treating physician
5. Vijoice oral granules will not be combined with Vijoice tablets
6. If the request is for Vijoice oral granules, the member's prescribed dose is 50mg daily, and the member will not use multiple 50mg packets per dose.

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for members requesting continuation of therapy when all of the following criteria are met:
1. Documentation that there is no evidence of unacceptable toxicity or disease progression (e.g., new lesions, progression of non-target lesions)
2. Documentation with chart notes or medical records that there is a positive response to therapy as evidenced by at least a 20% reduction in the lesion or lesions the approval was based upon and/or improvement in symptoms
2. Vijoice oral granules will not be combined with Vijoice tablets

3. If the request is for Vijoice oral granules, the member's prescribed dose is 50mg daily, and the member will not use multiple 50mg packets per dose.

IV. QUANTITY LIMIT

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

V. REFERENCES

1. Vijoice [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2024.