BlueCross BlueShield
Federal Employee Program

VIJOICE
(alpelisib)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 2 years of age or older

Diagnosis

Patient must have the following:

PIK3CA-Related Overgrowth Spectrum (PROS)

AND ALL of the following:

1. Confirmed mutation in the PIK3CA gene
2. Severe clinical manifestations and patient requires systemic treatment
3. Prescriber agrees to monitor for **ALL** of the following:
    a. Severe cutaneous reactions [e.g., Stevens-Johnson syndrome (SJS), erythema multiforme (EM), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS)]
    b. Pneumonitis
4. Prescriber agrees to monitor for elevated glucose and decrease the dose or discontinue therapy as required
5. Female patients of reproductive potential **only**: Prescriber agrees to advise patient to use effective contraception during treatment and for 1 week after the last dose
6. Male patients with female partners of reproductive potential **only**: Prescriber agrees to advise patient to use condoms and effective contraception during treatment and for 1 week after the last dose

Prior - Approval Limits

Quantity

Strength	Quantity Limit
250 mg blister packs (1 x 200 mg + 1 x 50 mg)	168 tablets per 84 days **OR**
125 mg blister packs (1 x 125 mg)	84 tablets per 84 days **OR**
50 mg blister packs (1 x 50 mg)	84 tablets per 84 days **OR**
50 mg granules	84 packets per 84 days

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VIJOICE
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Duration 12 months

Prior – Approval *Renewal* Requirements

Age 2 years of age or older

Diagnosis

Patient must have the following:

PIK3CA-Related Overgrowth Spectrum (PROS)

AND ALL of the following:

1. Confirmed mutation in the PIK3CA gene
2. **NO** disease progression or unacceptable toxicity
3. Prescriber agrees to monitor for **ALL** of the following:
    a. Severe cutaneous reactions [e.g., Stevens-Johnson syndrome (SJS), erythema multiforme (EM), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS)]
    b. Pneumonitis
4. Prescriber agrees to monitor for elevated glucose and decrease the dose or discontinue therapy as required
5. Female patients of reproductive potential **only**: Prescriber agrees to advise patient to use effective contraception during treatment and for 1 week after the last dose
6. Male patients with female partners of reproductive potential **only**: Prescriber agrees to advise patient to use condoms and effective contraception during treatment and for 1 week after the last dose

Prior - Approval *Renewal* Limits

Same as above