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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	April 29, 2022
Subject:	Vijoice	**Page:**	1 of 5

Last Review Date: March 7, 2025

Vijoice

Description

Vijoice (alpelisib)

Background
Vijoice (alpelisib) is an inhibitor of phosphatidylinositol-3-kinase (PI3K) with inhibitory activity predominantly against PI3Kα. Gain-of-function mutations in the gene encoding the α-subunit of PI3K (PIK3CA) leads to activation of PI3Kα and Akt-signaling, cellular transformation and the generation of tumors. Activating mutations in PIK3CA have been found to induce a spectrum of overgrowths and malformations comprising a wide group of clinically recognizable disorders commonly known as PIK3CA-Related Overgrowth Spectrum (PROS) (1).

Regulatory Status
FDA-approved indication: Vijoice is a kinase inhibitor 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 (1).

Vijoice has warnings regarding severe hypersensitivity, hyperglycemia, pneumonitis, diarrhea and severe cutaneous reactions. Severe cutaneous reactions, including Stevens-Johnson syndrome (SJS), erythema multiforme (EM), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) may occur in patients treated with Vijoice (1).

Vijoice may cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Vijoice and for 1 week after the last dose. Male patients with female partners of reproductive potential should be

advised to use condoms and effective contraception during treatment with Vijoice and for 1 week after the last dose (1).

The safety and effectiveness of Vijoice in pediatric patients less than 2 years of age have not been established (1).

Related policies
Joenja

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Vijoice may be considered **medically necessary** if the conditions indicated below are met.

Vijoice may be considered **investigational** for all other indications.

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 *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

Policy Guidelines

Pre - PA Allowance
None

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

Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary

Vijoice (alpelisib) is an inhibitor of phosphatidylinositol-3-kinase (PI3K) indicated for the treatment of PIK3CA-Related Overgrowth Spectrum (PROS). Vijoice has warnings regarding severe hypersensitivity, hyperglycemia, pneumonitis, diarrhea, fetal harm, and severe cutaneous reactions. The safety and effectiveness of Vijoice in pediatric patients less than 2 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Vijoice while maintaining optimal therapeutic outcomes.

References

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

Policy History

Date	Action
April 2022	Addition to PA

June 2022	Annual review
September 2022	Annual review
September 2023	Annual review and reference update
March 2024	Annual review. Per SME, added EM and TEN to requirement for monitoring severe cutaneous reactions
May 2024	Per PI update, added granule packets
June 2024	Annual review
September 2024	Annual review
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.