
5.21.192

| | | | |
|--------------------|-----------------------|------------------------------|----------------|
| Section: | Prescription Drugs | Effective Date: | July 1, 2022 |
| Subsection: | Antineoplastic Agents | Original Policy Date: | April 29, 2022 |
| Subject: | Vioice | Page: | 1 of 5 |

Last Review Date: June 16, 2022

Vioice

Description

Vioice (alpelisib)

Background

Vioice (alpelisib) is an inhibitor of phosphatidylinositol-3-kinase (PI3K) with inhibitory activity predominantly against PI3K α . Gain-of-function mutations in the gene encoding the α -subunit of PI3K (PIK3CA) leads to activation of PI3K α 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: Vioice 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).

Vioice 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 Vioice (1).

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

| | | | |
|--------------------|-----------------------|------------------------------|----------------|
| Section: | Prescription Drugs | Effective Date: | July 1, 2022 |
| Subsection: | Antineoplastic Agents | Original Policy Date: | April 29, 2022 |
| Subject: | Vijoice | Page: | 2 of 5 |

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

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** for patients 2 years of age or older with PIK3CA-Related Overgrowth Spectrum (PROS) and if the conditions indicated below are met.

Vijoice may be considered **investigational** in patients less than 2 years of age and 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, such as Stevens-Johnson syndrome (SJS) 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

| | | | |
|--------------------|-----------------------|------------------------------|----------------|
| Section: | Prescription Drugs | Effective Date: | July 1, 2022 |
| Subsection: | Antineoplastic Agents | Original Policy Date: | April 29, 2022 |
| Subject: | Vijoice | Page: | 3 of 5 |

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, such as Stevens-Johnson syndrome (SJS) 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

| | | | |
|--------------------|-----------------------|------------------------------|----------------|
| Section: | Prescription Drugs | Effective Date: | July 1, 2022 |
| Subsection: | Antineoplastic Agents | Original Policy Date: | April 29, 2022 |
| Subject: | Vijoice | Page: | 4 of 5 |

Prior - Approval Limits

Quantity

| Strength | Quantity Limit |
|--|-----------------------------------|
| 250 mg daily dose (1 x 200 mg + 1 x 50 mg) | 168 tablets per 84 days OR |
| 125 mg daily dose (1 x 125 mg) | 84 tablets per 84 days OR |
| 50 mg daily dose (1 x 50 mg) | 84 tablets 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 2022.

Policy History

| Date | Action |
|------------|----------------|
| April 2022 | Addition to PA |
| June 2022 | Annual review |

Keywords

5.21.192

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

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.