BlueCross BlueShield Federal Employee Program

# VIJOICE
# (alpelisib)

## RATIONALE FOR INCLUSION IN PA PROGRAM

### 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).

### 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.