Pharmacy Medical Necessity Guidelines:
Vijoice® (alpelisib)

Effective: March 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RxUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Vijoice (alpelisib) 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.

This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

COVERAGE GUIDELINES

The plan may authorize coverage of **Vijoice (alpelisib)** for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of PIK3CA-Related Overgrowth Spectrum

AND

2. The patient is at least 2 years of age or older

AND

3. Documentation the patient's condition is severe or life-threatening as determined by the treating physician

Reauthorization Criteria

1. Documented diagnosis of PIK3CA-Related Overgrowth Spectrum

AND

2. The patient is at least 2 years of age or older

AND

3. Documentation the patient has not experienced disease progression while receiving Vijoice

LIMITATIONS

- Initial approval by the plan will be limited to six (6) months. Reauthorization will be provided in 12-month intervals.
- Members new to the plan stable on Vijoice (alpelisib) should be reviewed against Reauthorization Criteria.

CODES

None

REFERENCES

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4. Mirzaa G, Graham JM Jr, Keppler-Noreuil K. PIK3CA-related overgrowth spectrum. In: Adam MP, Ardinger HH, Pagon RA, et al., eds. *GeneReviews*®. Seattle (WA): University of Washington, Seattle; August 15, 2013. Updated December 2021. Accessed April 11, 2022. https://www.ncbi.nlm.nih.gov/books/NBK153722/a.
5. Morin G, Degrugillier-Chopinet C, Vincent M, et al. Treatment of two infants with PIK3CA-related overgrowth spectrum by alpelisib. *J Exp Med*. 2022;219(3):e20212148. doi:10.1084/jem.20212148.
6. Pagliazzi A, Oranges T, Traficante G, et al. *PIK3CA*-related overgrowth spectrum from diagnosis to targeted therapy: A case of CLOVES syndrome treated with alpelisib. *Front Pediatr*. 2021;9:732836. doi:10.3389/fped.2021.732836.
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APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

1. July 11, 2023: No changes
2. May 14, 2024: No changes
3. March 11, 2025: No changes (eff 3/11/25)
4. March 10, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services