UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1388-5
Program	Prior Authorization/Notification
Medication	Vijoice® (alpelisib)
P&T Approval Date	6/2022, 6/2023, 6/2024, 6/2025, 6/2026
Effective Date	9/1/2026

1. Background:

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(s).

2. Coverage Criteria [a]:

A. Initial Authorization

1. **Vijoice** will be approved based on **all** of the following criteria:

   a. Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS)

   -AND-

   b. Patient is 2 years of age or older

   -AND-

   c. Patient has severe manifestations of PROS requiring systemic therapy

Authorization will be issued for 12 months.

B. Reauthorization

1. **Vijoice** will be approved based upon the following criterion:

   a. Documentation of positive clinical response to **Vijoice** therapy.

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits, Medical Necessity, and/or Step Therapy may be in place.

4. References:

1. Vijoice [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2025.

Program	Prior Authorization/Notification – Vijoice® (alpelisib)
Change Control	
6/2022	New program.
6/2023	Annual review. Added state mandate footnote. Updated references.
6/2024	Annual review. Updated initial authorization to 12 months. Updated references.
6/2025	Annual review without changes to coverage criteria.
6/2026	Annual review without changes to coverage criteria. Updated reference.

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