

<b>Clinical Policy Title:</b>	alpelisib
<b>Policy Number:</b>	RxA.767
<b>Drug(s) Applied:</b>	Vijoice®
<b>Original Policy Date:</b>	07/18/2022
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. PIK3CA-related overgrowth spectrum (PROS) (must meet all):

1. Diagnosis of severe manifestations associated with PIK3CA-related overgrowth spectrum (PROS);
2. Member has at least one target lesion identified on imaging;
3. Member must have documented evidence of a mutation in the PIK3CA gene.

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

### II. Continued Therapy Approval

#### A. PIK3CA-related overgrowth spectrum (PROS) (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy..

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

## References

Not applicable.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	06/02/2022	07/18/2022
Policy was Reviewed: <ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.3: Updated to add criteria prescribed by or in consultation with a physician who specializes in the treatment of PROS.</li> <li>2. Continued Therapy Criteria I.B: Updated approval duration from 6 months to 12 months.</li> <li>3. References were reviewed and updated.</li> </ol>	06/06/2023	07/13/2023

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage.	08/28/2024	09/13/2024
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025