

Policy Name:	Vijoice (alpelisib)	Policy #:	3165P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Vijoice (alpelisib).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Vijoice (alpelisib) under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for PIK3CA-Related Overgrowth Spectrum (PROS)

- 1.1 Documented diagnosis of PIK3CA-related overgrowth spectrum (PROS)
 - Must include evidence of PIK3CA gene mutation
- 1.2 Documentation that patient's condition is severe or life-threatening and treatment is deemed necessary as determined by the treating physician
- 1.3 Documentation supporting at least one target lesion identified on imaging scans performed within the previous 6 months
- 1.4 Age 2 years or older
- 1.5 Prescribed by or in consultation with a geneticist (doctor specializing in genes and heredity) or specialist in the treatment of PROS
- 1.6 Review of clinical documentation confirming that patient has met all of the above requirements for treatment is completed by both a pharmacist and a medical director

2. Managed Dose Limit

- 2.1 Tablet pack: #60 tablets per 30 days
- 2.2 Oral granule packs: #90 packets per 30 days, age max of 12 years

3. Approval Period

- 3.1 Initial: 12 months
- 3.2 Reauthorization: 12 months with documentation of positive response to therapy, as evidenced by documentation of at least a 20% reduction in the sum of measurable target lesion volume and without new lesion development

CPT Codes

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HCPCS Codes

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References

1. Vijoice (alpelisib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2022.
2. Venot Q, Blanc T, Rabia SH, et al. Targeted therapy in patients with PIK3CA-related overgrowth syndrome. *Nature*. 2018;558(7711):540-546.
3. Pagliuzzi 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 Sep 9;9:732836.
4. Raghavendran P, Albers SE, Phillips JD, et al. Clinical Response to PI3K- α Inhibition in a Cohort of Children and Adults With PIK3CA-Related Overgrowth Spectrum Disorders. *J Vasc Anom (Phila)*. 2022 Mar;3(1):e038.

5. National Center for Advancing Translational Sciences. Genetic and Rare Diseases Information Center. PIK3CA-related overgrowth spectrum. Updated January 2022. Accessed December 2022. <https://rarediseases.info.nih.gov/diseases/12182/pik3ca-related-overgrowth-spectrum>
6. National Organization for Rare Disorders. PIK3CA-related overgrowth spectrum. Updated July 10, 2018. Accessed December 2022. <https://rarediseases.org/rare-diseases/pik3ca-related-overgrowth-spectrum>

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.