Clinical Policy Title:	alpelisib
Policy Number:	RxA.767
Drug(s) Applied:	Vijoice®
Original Policy Date:	07/18/2022
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	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. Age ≥ 2 years;
3. Prescribed by or in consultation with a physician who specializes in the treatment of PROS;
4. Member has at least one target lesion identified on imaging;
5. Member must have documented evidence of a mutation in the PIK3CA gene;
6. Dose does not exceed (a, b or c):
   a. Age 2 to 5 years: 50 mg/day;
   b. Age 6 to 17 years: 50 mg/day to 125 mg/day;
   c. Adult patients: 250 mg/day;

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b or c):
   a. Age 2 to 5 years: 50 mg/day;
   b. Age 6 to 17 years: 125 mg/day;
   c. Adults: 250 mg/day;

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References
Not Applicable

Review/Revision History	Review/Revision Date	P&T Approval Date

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.

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Policy established.	06/02/2022	07/18/2022
Policy was Reviewed: 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. 2. Continued Therapy Criteria I.B: Updated approval duration from 6 months to 12 months. 3. References were reviewed and updated.	06/06/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023

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