

Vijoice (alpelisib)

Override(s)	Approval Duration
Prior Authorization	Initial requests: 6 months
Quantity Limit	Continuation requests: 1 year

Medications	Quantity Limit
Vijoice	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Vijoice (alpelisib) may be approved if the following criteria are met:

- I. Individual is 2 years of age or older; **AND**
- II. Individual has a diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) disorder defined as any of the following:
 - A. Fibroadipose hyperplasia; **OR**
 - B. CLOVES syndrome; **OR**
 - C. Megalencephaly-capillary malformation syndrome (MCAP syndrome); **OR**
 - D. Hemihyperplasia-multiple liomatosis syndrome (HHML syndrome); **OR**
 - E. Hemimegalencephaly; **OR**
 - F. Facial infiltrating lipomatosis;

AND

- III. Individual's PROS disorder requires systemic therapy; **AND**
- IV. Individual has a Karnofsky (in those greater than 16 years old)/Lansky (in those less than and equal to 16) performance status index of greater than or equal to 50; **AND**
- V. Has at least one PROS-related measurable lesion defined as a lesion with longest diameter ≥ 2 cm.

Continuation requests for Vijoice (alpelisib) may be approved if the individual has a response which may include:

- I. Reduction in size of PROS lesions; **OR**
- II. Improvement in signs and symptoms of PROS (e.g. growth of lesions, seizures, thrombotic events, pain, cognitive impairment).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 9, 2022
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 9, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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