COMMON GROUND
HEALTHCARE COOPERATIVE

PHARMACY POLICY STATEMENT
Common Ground Healthcare Cooperative (CGHC)

DRUG NAME	Vijoice (alpelisib)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Vijoice is a phosphatidylinositol-3-kinase (PI3K) 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. It was approved under the FDA accelerated approval pathway and is the first approved treatment for PROS. Existing treatment strategies include surgery, interventional radiology, and symptom management.
PROS is a group of rare conditions characterized by overgrowth of various parts of the body, caused by mutations in the *PIK3CA* gene which has a role in regulating cell growth and division. Mutation can result in uncontrolled growth of the affected tissue(s).
Vijoice was studied in the EPIK-P1 clinical trial, a retrospective chart review in 37 patients. In the study, 27% had a radiological response at week 24, and 60% had a response lasting at least 12 months.
Of note, alpelisib is marketed under the brand name Piqray for the treatment of breast cancer.

Vijoice (alpelisib) will be considered for coverage when the following criteria are met:

PIK3CA-Related Overgrowth Spectrum (PROS)

For **initial** authorization:
1. Member is at least 2 years of age; AND
2. Medication must be prescribed by or in consultation with an oncologist, geneticist, metabolic specialist, or dermatologist; AND
3. Member has a diagnosis of a PROS disorder confirmed by documentation of both of the following:
   a) Mutation of the *PIK3CA* gene*
   b) At least one measurable target lesion identified on imaging; AND
4. The physician has determined the member's condition is severe, life-threatening, or requires surgical intervention.
5. **Dosage allowed/Quantity limit:**
   Adults (18+): 250 mg by mouth once daily
   Pediatrics:

Patient age (years)	Initial dose	Dose increase
2 to < 6	50 mg	Not applicable*
6 to < 18	50 mg	125 mg

   QL: 56 tablets per 28 days

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If all the above requirements are met, the medication will be approved for 6 months. **Note: Although not all patients may present with a mutation, the drug was only studied in patients who met this criterion. There is no data available for using Vijoice in those without the mutation.*
For **reauthorization**: 1. Documentation must be provided to show at least 20% reduction in the sum of measurable target lesion volume from baseline; AND 2. No progression of non-target lesions; AND 3. No appearance of new lesions. ***If all the above requirements are met, the medication will be approved for an additional 6 months.***

CareSource considers Vijoice (alpelisib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/21/2022	New policy for Vijoice created.

References:

1. Vijoice. Prescribing information. Novartis Pharmaceuticals Corporation; 2022.
2. Retrospective Chart Review Study of Patients With PIK3CA-Related Overgrowth Spectrum Who Have Received Alpelisib (EPIK-P1). ClinicalTrials.gov Identifier: NCT04285723. Updated October 4, 2021, Accessed June 21, 2022. https://clinicaltrials.gov/ct2/show/NCT04285723
3. Keppler-Noreuil KM, Rios JJ, Parker VE, et al. PIK3CA-related overgrowth spectrum (PROS): diagnostic and testing eligibility criteria, differential diagnosis, and evaluation. *Am J Med Genet A*. 2015;167A(2):287-295. doi:10.1002/ajmg.a.36836
4. Canaud G, Hammill AM, Adams D, Vikkula M, Keppler-Noreuil KM. A review of mechanisms of disease across PIK3CA-related disorders with vascular manifestations. *Orphanet J Rare Dis*. 2021;16(1):306. Published 2021 Jul 8. doi:10.1186/s13023-021-01929-8
5. Keppler-Noreuil KM, Parker VE, Darling TN, Martinez-Agosto JA. Somatic overgrowth disorders of the PI3K/AKT/mTOR pathway & therapeutic strategies. *Am J Med Genet C Semin Med Genet*. 2016;172(4):402-421. doi:10.1002/ajmg.c.31531
6. Douzgou S, Rawson M, Baselga E, et al. A standard of care for individuals with PIK3CA-related disorders: An international expert consensus statement. *Clin Genet*. 2022;101(1):32-47. doi:10.1111/cge.14027
7. Venot Q, Blanc T, Rabia SH, et al. Targeted therapy in patients with PIK3CA-related overgrowth syndrome [published correction appears in Nature. 2019 Apr;568(7752):E6]. *Nature*. 2018;558(7711):540-546. doi:10.1038/s41586-018-0217-9

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