

Commercial PA Criteria

Effective: June 17, 2022

Prior Authorization: Vioice

Products Affected: Vioice (alpelisib) oral tablets

Medication Description: Vioice is a kinase 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.

Covered Uses: PIK3CA-related overgrowth spectrum: Treatment of severe manifestations of PIK3CA-related overgrowth spectrum in patients ≥ 2 years of age who require systemic therapy.

Exclusion Criteria: None

Required Medical Information:

1. Diagnosis

Prescriber Restriction: Prescribed by, or in consultation with, a physician that specializes in treatment of genetic disorders

Age Restriction: 2 years of age and older

Coverage Duration: Initial- 6 months. Continuation- 12 months

Other Criteria:

Initial Approval Criteria

1. **PIK3CA-Related Overgrowth Spectrum (PROS).** Approve for 6 months if the patient meets the following criteria (A **AND** B):

Note: Examples of PROS include congenital lipomatous overgrowth, vascular malformations, epidermal nevi, scoliosis/skeletal and spinal (CLOVES) syndrome; megalencephaly-capillary malformation (MCAP) syndrome; Klippel-Trenaunay syndrome (KTS); facial infiltrating lipomatosis (FIL), dysplastic megalencephaly (DMEG); hemimegalencephaly (HMEG); focal cortical dysplasia (FCD); or capillary vascular malformation of the lower lip, lymphatic malformations of the head and neck, asymmetry and partial or generalized overgrowth (CLAPO) syndrome.

- A. Patient has at least one severe clinical manifestation of PROS, as determined by the prescriber; **AND**

Note: Examples of severe clinical manifestations include excessive tissue growth, blood vessel malformations, scoliosis, vascular tumors, cardiac or renal manifestations, and those that require systemic treatment.

- B. Patient has a PIK3CA mutation as confirmed by genetic testing

Renewal Criteria

1. **Patient is Currently Receiving Vioice.** Approve for 12 months if the patient meets the following criteria (A,B **and** C):
 - A. Patient has been established on Vioice for at least 6 months; **AND**
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Vioice is reviewed under criterion A (Initial Therapy).
 - B. Patient has experienced a reduction in volume from baseline (prior to initiating Vioice) in at least one lesion, as confirmed by measurement; **AND**

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- C. Patient has experienced an improvement in at least one sign or symptom of PROS from baseline (prior to initiating Vijoje).

Note: Examples of signs or symptoms of PROS include pain, fatigue, vascular malformation, limb asymmetry, or disseminated intravascular coagulation.

References:

1. Vijoje® tablets [prescribing information]. East Hanover, NJ: Novartis; April 2022

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	6/17/2022

