Louisiana Medicaid
Alpelisib (Vijoice®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for alpelisib (Vijoice®)

Additional Point-of-Sale edits may apply.

*This agent may have **Black Box Warnings**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

VIJOICE 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. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Approval Criteria

- The recipient is 2 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) confirmed by documented evidence of mutation in the PIK3CA gene; **AND**
- The prescriber **states on the request** that the recipient has clinical manifestations of PROS that are severe or life-threatening and necessitating systemic treatment; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a geneticist or a physician who specializes in the treatment of PROS; **AND**
- If the request is for a non-preferred agent - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested

medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial criteria; **AND**
- The prescriber **states on the request** that there is evidence of a positive radiological response to therapy defined by a ≥ 20% reduction from baseline in the sum of measurable target lesion volume (one to three lesions, via central review of imaging scans), confirmed by at least one subsequent imaging assessment and if none of the individual target lesions have ≥ 20% increase from index date and absence of disease progression.

Duration of initial and reauthorization approval: 6 months

Reference

Vijoice (alpelisib) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215039s000lbl.pdf

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