| Reference number(s) |
| --- |
| 5360-A |

# Specialty Guideline Management
# Vijoice

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Vijoice | alpelisib |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications[1]

Vijoice is 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.

All other indications are considered experimental/investigational and not medically necessary.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review: Documentation of test confirming presence of PIK3CA gene mutation.

| Reference number(s) |
| --- |
| 5360-A |

# Coverage Criteria

## PIK3CA-related overgrowth spectrum (PROS)[1]

Authorization of 6 months may be granted for treatment of PROS when all of the following criteria are met:

- The member is at least 2 years of age.
- The member has severe manifestations of disease and requires systemic therapy.
- The member has a PIK3CA mutation.

# Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

# References

1. Vijoice [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2024.