Reference number(s)
3089-A

SPECIALTY GUIDELINE MANAGEMENT

PIQRAY (alpelisib)

POLICY

I. 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.

A. FDA-Approved Indication
Piqray is indicated in combination with fulvestrant for the treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

B. Compendial Uses
Breast cancer: Therapy for recurrent HR-positive, HER2-negative, PIK3CA mutated disease

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Documentation of test confirming presence of PIK3CA mutation
B. Documentation of HR and HER2 status

III. CRITERIA FOR INITIAL APPROVAL

Breast cancer
Authorization of 12 months may be granted for treatment of HR-positive, HER2-negative, PIK3CA-mutated recurrent, advanced or metastatic breast cancer when all of the following criteria are met:
A. The requested drug is used in combination with fulvestrant
B. Disease has progressed while on or after an endocrine-based regimen

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

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

2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 6, 2023.