Reference number(s)
3089-A

Specialty Guideline Management
Piqray

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
Piqray	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]

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.

Compendial Uses[2]

Breast cancer

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:

- Hormone Receptor (HR) status
- Human epidermal growth factor receptor 2 (HER2) status
- PIK3CA mutation status

Coverage Criteria

Breast Cancer[1-2]

Authorization of 12 months may be granted for treatment of HR-positive, HER2-negative, PIK3CA-mutated recurrent unresectable, advanced, or metastatic breast cancer when all of the following criteria are met:

- The requested drug is used in combination with fulvestrant
- Disease has progressed while on or after an endocrine-based regimen

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 section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Piqray [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 3, 2025.