

Piqray (alpelisib)

| Override(s) | Approval Duration |
|---------------------------------------|-------------------|
| Prior Authorization Quantity Limit | 1 year |

| Medications | Quantity Limit |
|----------------------------|----------------------------------|
| Piqray (alpelisib) tablets | May be subject to quantity limit |

APPROVAL CRITERIA

Requests for Piqray (alpelisib) may be approved if the following criteria are met (Label, NCCN 1):

- I. Individual has a diagnosis of recurrent, advanced, or metastatic breast cancer with hormone receptor (HR)-positive, human epithelial growth factor receptor 2 (HER2)-negative, and PIK3CA-mutated disease; **AND**
- II. Individual is using in combination with fulvestrant (Faslodex) with progression following endocrine therapy; **AND**
- III. Individual has PIK3CA mutation.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 13, 2025.
 - a. Breast Cancer. V6.2024. Revised November 11, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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