

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 with test results confirmed.

Requests for Piqray (alpelisib) may not be approved when the above criteria are not met and for all other indications.

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>. Accessed: December 23, 2020.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on December 23, 2020.
 - a. Breast Cancer. V6.2020. Revised September 8, 2020.

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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