

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

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

- I. Individual has a diagnosis of 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 confirmed PIK3CA mutation using an FDA-approved test (such as the *therascreen*® PIK3CA RGQ PCR Kit).

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

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

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: May 31, 2019.

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New Program Date 07/13/2019

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Applicable	X	X	X	X	X	X	X

2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on May 31, 2019.
 - a. Breast Cancer. V1.2019. Revised March 14, 2019.

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