ALPELISIB

Generic	Brand	HICL	GCN	Exception/Other
ALPELISIB	PIQRAY	45761		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative and meet **ALL** of the following criteria?
   - The patient is a postmenopausal female or male
   - Piqray will be used in combination with Faslodex (fulvestrant)
   - The patient has presence of PIK3CA-mutation as detected by an FDA-approved test
   - The patient has experienced disease progression on or after an endocrine-based regimen

   If yes, **approve for 12 months by GPID for all strengths as follows:**
   - **Piqray 300mg daily dose (GPID 46358): #56 per 28 days.**
   - **Piqray 250mg daily dose (GPID 46359): #56 per 28 days.**
   - **Piqray 200mg daily dose (GPID 46362): #28 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: The guideline named **ALPELISIB (Piqray)** requires a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative. In addition, the following criteria must be met:
   - The patient is a postmenopausal female or male
   - Piqray will be used in combination with Faslodex (fulvestrant)
   - The patient has presence of PIK3CA-mutation as detected by an FDA-approved test
   - The patient has experienced disease progression on or after an endocrine-based regimen

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Piqray.

REFERENCES
- Piqray [Prescribing Information]. East Hanover, NJ. Novartis Pharmaceuticals Corp., May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/19
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P&T Approval: 07/19