BlueCross BlueShield Federal Employee Program

PIQRAY
(alpelisib)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Advanced or metastatic breast cancer

AND ALL of the following:

1. Hormone receptor (HR)-positive
2. Human epidermal growth factor receptor 2 (HER2)-negative
3. PIK3CA-mutated as detected by an FDA-approved test
4. Used in combination with fulvestrant (Faslodex)
5. Patient has had disease progression on or after an endocrine-based regimen
6. Prescriber agrees to monitor for **ALL** of the following:
    a. Severe cutaneous reactions, such as Stevens-Johnson syndrome (SJS) and drug reaction with eosinophilia and systemic symptoms (DRESS)
    b. Pneumonitis
7. Prescriber agrees to monitor for elevated glucose and decrease the dose or discontinue therapy as required
8. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Piqray and for 1 week after the last dose
9. Male patients with female partners of reproductive potential **only**: patient will be advised to use condoms and effective contraception during treatment and for 1 week after the last dose

Prior - Approval Limits

Quantity

Strength	Quantity Limit
300 mg daily dose (2 x 150 mg)	168 tablets per 84 days **OR**
250 mg daily dose (1 x 200 mg + 1 x 50 mg)	168 tablets per 84 days **OR**

200 mg daily dose (1 x 200 mg)	84 tablets per 84 days

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Advanced or metastatic breast cancer

AND ALL of the following:

1. Used in combination with fulvestrant (Faslodex)
2. **NO** disease progression or unacceptable toxicity
3. Prescriber agrees to monitor for **ALL** of the following:
    a. Severe cutaneous reactions, such as Stevens-Johnson syndrome (SJS) and drug reaction with eosinophilia and systemic symptoms (DRESS)
    b. Pneumonitis
4. Prescriber agrees to monitor for elevated glucose and decrease the dose or discontinue therapy as required
5. Female patients of reproductive potential only: patient will be advised to use effective contraception during treatment with Piqray and for 1 week after the last dose
6. Male patients with female partners of reproductive potential **only**: patient will be advised to use condoms and effective contraception during treatment and for 1 week after the last dose

Prior - Approval *Renewal* Limits

Same as above

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