Piqray

Description

Piqray (alpelisib)

Background
Piqray (alpelisib) is an inhibitor of phosphatidylinositol-3-kinase (PI3K) with inhibitory activity predominantly against PI3Kα. In breast cancer cell lines, alpelisib inhibited the phosphorylation of PI3K downstream targets, including Akt and showed activity in cell lines harboring a PIK3CA mutation. PI3K inhibition by alpelisib treatment has been shown to induce an increase in estrogen receptor (ER) transcription in breast cancer cells. The combination of alpelisib and fulvestrant demonstrated increased anti-tumor activity compared to either treatment alone (1).

Regulatory Status
FDA approved indication: Piqray is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen (1).

Piqray has a warning for severe cutaneous reactions. Severe cutaneous reactions, including Stevens-Johnson Syndrome (SJS) and Erythema Multiforme (EM) were reported in patients treated with Piqray (1).

Piqray may cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Piqray and for 1 week after the last dose. Male patients with female partners of reproductive potential should be
advised to use condoms and effective contraception during treatment with Piqray and for 1 week after the last dose (1).

The safety and effectiveness of Piqray in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Piqray may be considered medially necessary for patients 18 years of age or older with breast cancer and if the conditions indicated below are met.

Piqray may be considered investigational in patients less than 18 years of age and for all other indications.

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. Female patients must be postmenopausal
5. Used in combination with fulvestrant (Faslodex)
6. Patient has had disease progression on or after an endocrine-based regimen
7. Prescriber agrees to monitor for ALL of the following:
   a. Stevens-Johnson syndrome (SJS)
b. Pneumonitis
8. Prescriber agrees to monitor for elevated glucose and decrease the dose or discontinue therapy as required
9. Female patients of reproductive potential and male patients with female partners of reproductive potential only: Prescriber agrees to advise patient to use effective contraception during treatment and for 1 week after the last dose

### 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. Stevens-Johnson syndrome (SJS)
   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 and male patients with female partners of reproductive potential only: Prescriber agrees to advise patient to use effective contraception during treatment and for 1 week after the last dose

### Policy Guidelines

**Pre - PA Allowance**
None

**Prior - Approval Limits**

**Quantity**
Rationale

Summary

Piqray (alpelisib) is an inhibitor of phosphatidylinositol-3-kinase (PI3K) with inhibitory activity predominantly against PI3K. In breast cancer cell lines, alpelisib inhibited the phosphorylation of PI3K downstream targets, including Akt and showed activity in cell lines harboring a PIK3CA mutation. PI3K inhibition by alpelisib treatment has been shown to induce an increase in estrogen receptor (ER) transcription in breast cancer cells. The combination of alpelisib and fulvestrant demonstrated increased anti-tumor activity compared to either treatment alone. The safety and effectiveness of Piqray in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Piqray while maintaining optimal therapeutic outcomes.

References

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.