



## **RATIONALE FOR INCLUSION IN PA PROGRAM**

### **Background**

Piqray (alpelisib) is an inhibitor of phosphatidylinositol-3-kinase (PI3K) with inhibitory activity predominantly against PI3K $\alpha$ . 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 adults 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 warnings regarding severe hypersensitivity, hyperglycemia, pneumonitis, diarrhea, and severe cutaneous reactions. Severe cutaneous reactions, including Stevens-Johnson syndrome (SJS), erythema multiforme (EM), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) 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).

### **Summary**

Piqray (alpelisib) is an inhibitor of phosphatidylinositol-3-kinase (PI3K) indicated in combination with fulvestrant for the treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer.



**BlueCross  
BlueShield**

Federal Employee Program.

**PIQRAY  
(alpelisib)**

Piqray has warnings regarding severe hypersensitivity, hyperglycemia, pneumonitis, diarrhea, fetal harm and severe cutaneous reactions. 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**

1. Piqray [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.
2. NCCN Drugs & Biologics Compendium® Alpelisib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 8, 2025.