UnitedHealthcare

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1290-5
Program	Prior Authorization/Notification
Medication	Piqray® (alpelisib)
P&T Approval Date	8/2019, 8/2020, 8/2021, 8/2022, 8/2023
Effective Date	11/1/2023

1. **Background:**

   Piqray (alpelisib) is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, premenopausal women treated with ovarian ablation/suppression, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen.[1]

   Coverage Information:
   Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

   Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. **Coverage Criteria[a]:**

   > **A. Patients less than 19 years of age**
   >
   >   1. **Piqray** will be approved based on the following criterion:
   >
   >   a. Patient is less than 19 years of age
   >
   >   **Authorization will be issued for 12 months.**
   >
   > **B. Breast Cancer**
   >
   >   1. **Initial Authorization**
   >
   >   a. **Piqray** will be approved based on **all** of the following criteria:
   >
   >   (1) Diagnosis of breast cancer
   >
   >   -AND-
   >
   >   (2) **One** of the following:
   >
   >   (a) Advanced
   >   (b) Metastatic

-AND-

(3) Disease is hormone receptor (HR)-positive

-AND-

(4) Disease is human epidermal growth factor receptor 2 (HER2)-negative

-AND-

(5) Presence of one or more PIK3CA mutations

-AND-

(6) Patient is one of the following:

    (a) Postmenopausal
    (b) Premenopausal with ovarian ablation/suppression
    (c) Male

-AND-

(7) Used in combination with fulvestrant

-AND-

(8) Disease has progressed on or after an endocrine-based regimen

Authorization will be issued for 12 months.

2. **Reauthorization**

    a. **Piqray** will be approved based on the following criterion:

        (1) Patient does not show evidence of progressive disease while on **Piqray** therapy.

    Authorization will be issued for 12 months.

C. **NCCN Recommended Regimens**

1. The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. **Additional Clinical Rules:**

    - Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
    - Supply limits may be in place.

4. **References:**

    1. Piqray [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. November 2022.
    2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed June 28, 2023.

Program	Prior Authorization/Notification – Piqray (alpelisib)
Change Control	
8/2019	New program.
8/2020	Annual review. Updated formatting without change to clinical intent of program. Updated reference.
8/2021	Annual review with no changes to coverage criteria. Updated references.
8/2022	Annual review. Updated coverage criteria for initial authorization for breast cancer to include premenopausal women treated with ovarian ablation/suppression per NCCN Guidelines. Updated references.
8/2023	Annual review with no changes to coverage criteria. Updated references.