PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Piqray Prior Authorization Policy
- Piqray® (alpelisib tablets – Novartis)

REVIEW DATE: 07/13/2022

OVERVIEW

Piqray, a kinase inhibitor, is indicated in combination with fulvestrant injection for the treatment of postmenopausal women and men with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, phosphatidylinositol-3-kinase (*PIK3CA*)-mutated, **advanced or metastatic breast cancer** as detected by an FDA-approved test following progression on or after an endocrine-based regimen.[1] Patients treated with Piqray should have one or more *PIK3CA* mutations in tumor tissue or plasma specimens. If no mutation is detected in a plasma specimen, tumor tissue should be tested. Information on FDA-approved tests for the detection of *PIK3CA* mutations in breast cancer is available on the FDA website.[2]

Guidelines

Piqray is discussed in the guidelines from National Comprehensive Cancer Network (NCCN).[3-4] NCCN breast cancer guidelines (version 4.2022 – June 21, 2022) recommend Piqray, in combination with fulvestrant, as a preferred second-line regimen or subsequent-line therapy for *PIK3CA*-mutated tumors in postmenopausal or premenopausal patients (receiving ovarian ablation or suppression, if premenopausal) with HR+/HER2-negative, recurrent unresectable (local or regional) or Stage IV disease (category 1).[3] It is noted that the safety of Piqray in patients with type 1 or uncontrolled type 2 diabetes has not been established. Preferred first-line regimens for HR+/HER2-negative disease include the following: aromatase inhibitor (i.e., letrozole, anastrozole, exemestane) + CDK4/6 inhibitor (i.e., Ibrance® [palbociclib capsules], Kisqali® [ribociclib tablets], Verzenio® [abemaciclib tablets]), fulvestrant with or without non-steroidal aromatase inhibitor (anastrozole or letrozole), fulvestrant + CDK4/6 inhibitor (all category 1); fulvestrant monotherapy, non-steroidal aromatase inhibitor monotherapy, tamoxifen, or exemestane (all category 2A). Of note, men with breast cancer are treated similarly to postmenopausal women.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Piqray. All approvals are provided for the duration noted below. In the clinical criteria, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression; men are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Piqray is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Breast Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, E, F, and G):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets one of the following criteria (i or ii):
     - **i.** Patient is a postmenopausal female* or a male*; OR
     - **ii.** Patient is pre/perimenopausal and meets one of the following criteria (a or b):
       - **a)** Patient is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) agonist; OR
         Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection).
       - **b)** Patient has had surgical bilateral oophorectomy or ovarian irradiation; AND
   - **C)** Patient has advanced or metastatic hormone receptor (HR)-positive disease; AND
   - **D)** Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; AND
   - **E)** Patient has *PIK3CA*-mutated breast cancer as detected by an approved test; AND
   - **F)** Patient has progressed on or after at least one prior endocrine-based regimen; AND
     Note: Examples of an endocrine-based regimen contains one of the following products: anastrozole, letrozole, exemestane, tamoxifen, toremifene, or fulvestrant.
   - **G)** Piqray will be used in combination with fulvestrant injection.

   * Refer to Policy Statement

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Piqray is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Piqray® tablets [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2020.
2. Food and Drug Administration. Lists of cleared or approved companion diagnostic devices (in vitro and imaging tools). Available at: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools. Accessed on July 7, 2022.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2022 – June 21, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 7, 2022
4. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 7, 2022. Search term: alpelisib.