EXPRESS SCRIPTS®

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Piqray® (alpelisib tablets – Novartis Pharmaceuticals Corporation)

TAC APPROVAL DATE: 05/29/2019; selected revision 07/10/2019

OVERVIEW

Piqray is indicated in combination with Faslodex (fulvestrant for 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

The National Comprehensive Cancer Network (NCCN) guidelines on breast cancer (version 2.2019 – July 2, 2019) recommend Piqray, in combination with Faslodex, as a preferred regimen (category 1) for *PIK3CA*-mutated tumors in postmenopausal or premenopausal patients (receiving ovarian ablation or suppression, if premenopausal) with HR+/HER2-negative, recurrent or Stage IV disease.8 It is noted that the safety of Piqray in patients with Type 1 or uncontrolled Type 2 diabetes has not been established. Other preferred regimens for HR+/HER2-negative disease include the following: Faslodex, aromatase inhibitor (i.e., letrozole, anastrozole, exemestane) + CDK4/6 inhibitor (i.e., Ibrance® [palbociclib capsules], Kisqali® [ribociclib tablets], Verzenio™ [abemaciclib tablets]), Faslodex + CDK4/6 inhibitor (all category 1), aromatase inhibitor monotherapy, tamoxifen or toremifene, exemestane + Afinitor® (everolimus tablets), Faslodex + Afinitor, and tamoxifen + Afinitor (all category 2A). According to the guidelines, other agents "useful in certain circumstances" include the following: Kisqali + tamoxifen (category 1), megestrol acetate, fluoxymesterone, ethinyl estradiol, and Verzenio (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 Indications

1. **Breast Cancer.** Approve for 3 years if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** The patient meets one of the following criteria (i or ii):
     - **i.** The patient is a postmenopausal female* or a male*; OR
     - **ii.** The patient is premenopausal* and is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) agonist or has had surgical bilateral oophorectomy or ovarian irradiation.
       Note: Examples include Lupron/Lupron Depot (leuprolide acetate injectable suspension), Trelstar (triptorelin pamoate injectable suspension), Zoladex (goserelin acetate implant); AND
   - **B)** The patient has advanced or metastatic hormone receptor (HR)-positive disease; AND
   - **C)** The patient has human epidermal growth factor receptor 2 (HER2)-negative disease; AND
   - **D)** The patient has *PIK3CA*-mutated breast cancer as detected by an approved test; AND
   - **E)** The patient has progressed on or after at least one prior endocrine-based regimen.
     Note: Examples include anastrozole, letrozole, exemestane, Faslodex, tamoxifen, toremifene.

* Refer to Policy Statement

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Piqray has not been shown to be effective or there are limited or preliminary data that are not supportive of general approval for the following conditions.

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.; May 2019.
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 May 21, 2019.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 2.2019 – July 2, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 5, 2019.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
New policy	--	05/29/2019
Selected revision	Added approval criteria for use of Piqray for breast cancer in premenopausal females based on guideline recommendations.	07/10/2019

TAC – Therapeutic Assessment Committee. * For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx.