MEDICAL MUTUAL

Drug Policy

Policy:	Piqray (alpelisib)	Annual Review Date: 06/18/2020 Last Revised Date: 06/18/2020

OVERVIEW

Piqray, a kinase inhibitor, 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, 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. 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. The NCCN Breast Cancer clinical practice guidelines (version 1.2019) have not yet discussed the use of Piqray in the treatment guidelines.

POLICY STATEMENT

This policy involves the use of Piqray. Prior authorization is recommended for pharmacy benefit coverage of Piqray. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Piqray as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Piqray be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Piqray must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. <u>Breast Cancer</u>

Criteria. *Patient must meet the following criteria:*

A. The patient is a postmenopausal female OR a male OR a premenopausal woman treated with ovarian ablation/suppression; AND

B. The patient has advanced or metastatic breast cancer; AND

C. The patient has HR-positive disease; AND
D. The patient has HER2-negative disease; AND
E. The patient has PIK3CA-mutated breast cancer as detected by a FDA approved test; AND
F. The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen, toremifene); AND
G. Piqray will be used in combination with fulvestrant

2. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

3. **Patient has been started on Piqray**
Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 days (1 year)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Piqray has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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 17 June 2019.
3. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed 4 June 2020.
4. Alpelisib. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 21 May 2020. Accessed on 4 June 2020.