PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/04/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Piqray, a kinase inhibitor, is indicated in combination with fulvestrant injection for the treatment of 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 in adults.[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 the National Comprehensive Cancer Network (NCCN).[3,4] NCCN breast cancer guidelines (version 4.2025 – April 17, 2025)

recommend Piqray, in combination with fulvestrant, as a "preferred" second-line regimen or subsequent-line therapy for *PIK3CA*-activating mutation 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 men with breast cancer should be treated similarly to postmenopausal women, except that use of an aromatase inhibitor is ineffective without concomitant suppression of testicular steroidogenesis. 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]) or fulvestrant + CDK4/6 inhibitor.

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.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Breast Cancer.** Approve for 1 year if the patient meets the following (A, B, C, D, E, F, and G):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient is a postmenopausal female* or a male*; OR
     - **ii.** Patient is pre/perimenopausal and meets ONE of the following (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 COVERED

- **Piqray® (alpelisib tablets - Novartis)**

is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Piqray® tablets [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.
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 30, 2025.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2025 – April 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 30, 2025.
4. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 30, 2025. Search term: alpelisib.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	07/12/2023
Update	**02/01/2024**: The FDA labeled indication was recently expanded to include "pre/perimenopausal women" so the wording was updated from "postmenopausal women and men" to "adult."	--
Annual Revision	No criteria changes.	06/12/2024
Annual Revision	No criteria changes.	06/04/2025