BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

IBRANCE® (palbociclib)
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for IBRANCE (palbociclib)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a physician specializing in the diagnosis or in consultation with an oncologist

Indication
- Diagnosis of **ONE** of the following:
  - Hormone receptor positive, human epidermal growth factor receptor 2 negative advanced or metastatic breast cancer in combination with **ONE** of the following:
    1. An aromatase inhibitor as initial endocrine-based therapy

2. Fulvestrant in those with disease progression following endocrine based therapy
   - Endocrine resistant, *PIK3CA* mutated, hormone receptor positive, human epidermal growth factor receptor 2 negative, locally advanced or metastatic breast cancer in combination with inavolisib and fulvestrant following recurrence on or after completing adjuvant endocrine therapy
   - Other oncologic direct treatment use listed in National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 or 2A

Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Complete blood count
- Negative pregnancy test in a woman of childbearing potential
- *PIK3CA* mutation status determined using the FoundationOne® Liquid CDx assay on plasma derived circulating tumor DNA (ctDNA) or using various validated polymerase chain reaction (PCR) or next generation sequencing (NGS) assays on tumor tissue or plasma

Brand Specific Criteria
- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- No concomitant drug use with strong CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine)
- Is not on hemodialysis

Additional Requirements
- Pre/perimenopausal women receiving Ibrance with an aromatase inhibitor, fulvestrant, or inavolisib should also receive luteinizing hormone releasing hormone (LHRH) agonists according to current clinical practice standards
- Men receiving Ibrance with an aromatase inhibitor, or Ibrance with inavolisib and fulvestrant, consider use with a luteinizing hormone releasing hormone (LHRH) agonists according to current clinical practice standards

Documentation Requirements
- A completed request form must be submitted including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

PHARMACY COVERAGE GUIDELINE

IBRANCE® (palbociclib)
Generic Equivalent (if available)

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualification

- Continues to be seen by a physician specializing in or is in consultation with an oncologist

Clinical Response

- Positive clinical response defined as no evidence of disease progression or unacceptable toxicity

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- No significant adverse drug effects that may exclude continued use such as:
  - Severe or life threatening neutropenia or febrile neutropenia
  - Severe or life threatening interstitial lung disease or pneumonitis
- No concomitant drug use with strong CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine)
- Is not on hemodialysis

Additional Requirements

- Requested dose is at least 75 mg daily for 21 days followed by 7 days off treatment within a 28 day cycle
- Pre/perimenopausal women receiving Ibrance with an aromatase inhibitor, fulvestrant, or inavolisib should also receive luteinizing hormone releasing hormone (LHRH) agonists according to current clinical practice standards
- Men receiving Ibrance with an aromatase inhibitor, or Ibrance with inavolisib and fulvestrant, consider use with a luteinizing hormone releasing hormone (LHRH) agonists according to current clinical practice standards

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use from above criteria

Continuation Therapy Criteria Approval Duration

- 6 months OR end of plan year

PHARMACY COVERAGE GUIDELINE

IBRANCE® (palbociclib)
Generic Equivalent (if available)

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications

2. Off-Label Use of Cancer Medications

Description:

Ibrance (palbociclib) is a kinase inhibitor indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with letrozole as initial endocrine based therapy in postmenopausal women, or fulvestrant in women with disease progression following endocrine therapy. Ibrance (palbociclib) is also indicated in combination with inavolisib and fulvestrant for the treatment of adult patients with endocrine resistant, *PIK3CA*-mutated, HR-positive, HER2-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy.

Palbociclib is the first oral cyclin-dependent kinase (CDK) inhibitor that works by blocking the action of enzymes called kinases. Kinases are involved in numerous cellular functions, including cell signaling, growth, and division. The majority of breast cancers are hormone receptor positive. They are stimulated to grow by the circulating female hormones estrogen and/or progesterone. Treatment of hormone receptor-positive breast cancer often involves hormonal therapies that suppress or block the action of estrogen. Growth of hormone-receptor–positive breast cancer is also dependent on the cyclin-dependent kinases 4 and 6 (CDK4 and CDK6), which promote progression through the various phases of the cell cycle that result in cell division. Specifically, palbociclib inhibits CDK4 and CDK6.

Letrozole is a nonsteroidal competitive inhibitor of the aromatase enzyme system; it inhibits the conversion of androgens to estrogens. Fulvestrant is an estrogen receptor antagonist that binds to the estrogen receptor (ER) and downregulates the ER protein in human breast cancer cells, blocking the actions of estrogen.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Aromatase Inhibitors:
Arimidex (anastrozole)
Femara (letrozole)
Aromasin (exemestane)

Antiestrogens:
Faslodex (fulvestrant)
Tamoxifen

Fareston (toremifene)

Gonadotropin-Releasing Hormone Analog – for men with breast cancer along with aromatase inhibitors:
Zoladex (goserelin)
Vantas (histrelin)
Eligard, Lupron (leuprolide)
Trelstar (triptorelin)
Progestin Combination

Antiandrogens:
Zytiga, Yonsa (abiraterone)
Erleada (apalutamide)
Casodex (bicalutamide)
Xtandi (enzalutamide)
Flutamide
Nilandron (nilutamide)

ECOG Performance status:

Eastern Co-operative Oncology Group (ECOG) Performance Status	
Grade	ECOG description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead
Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982	

NCCN recommendation definitions:
Category 1:
Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A:
Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B:
Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3:
Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0:

Grade 1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated

Grade 2	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL*
Grade 3	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL**
Grade 4	Life-threatening consequences; urgent intervention indicated
Grade 5	Death related to AE
U.S. department of Health and Human Services, National Institutes of Health, and National Cancer Institute	

Resources:

Ibrance (palbociclib) capsule product information, revised by Pfizer Laboratories Div Pfizer Inc. 09-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 29, 2026.

Ibrance (palbociclib) tablet product information, revised by Pfizer Laboratories Div Pfizer Inc. 09-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 29, 2026.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Breast Cancer Version 2.2026 – Updated February 27, 2026. Available at https://www.nccn.org. Accessed March 13, 2026.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.