BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 3/17/16**
SECTION: DRUGS	**LAST REVIEW DATE: 3/15/18**
	LAST CRITERIA REVISION DATE: 3/15/18
	ARCHIVE DATE:

IBRANCE® (palbociclib) oral capsule

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

IBRANCE® (palbociclib) oral capsule (cont.)

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.

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.

Ibrance (palbociclib)

Medication class:
Antineoplastic Agent; Cyclin-Dependent Kinase Inhibitor

FDA-approved indication(s):
- Treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in combination with:
  - An aromatase inhibitor as initial endocrine based therapy in postmenopausal women OR
  - Fulvestrant in women with disease progression following endocrine therapy

Recommended Dose:
- 125 mg once daily for 21 days, then off for 7 days

Maximum dosage
- Bullet 2

Available Dosage Forms:
- 75 mg, 100 mg, 125 mg caps

Warnings, Precautions, and other Clinical Information:
- Interrupt dose or dose reduction or delay in starting a treatment cycle is dependent on development and severity of neutropenia
- If an individual is intolerant to 75 mg once daily, Ibrance should be discontinued
- Reduce dose to 75 mg once daily in patients with severe hepatic impairment (Child-Pugh Class C)
- If use of a strong CYP3A4 inhibitor cannot be avoided, reduce Ibrance dose

IBRANCE® (palbociclib) oral capsule (cont.)

- Avoid simultaneous use with strong CYP3A inducers such as phenytoin, rifampin, carbamazepine, enzalutamide, and St. John's wort
- Woman of child bearing potential should have a pregnancy test done before treatment with Ibrance
- Woman of child bearing potential should be warned against becoming pregnant
- Woman of child bearing potential should use effective contraception
- Woman who is breast feeding an infant or child should stop breast feeding
- Male patient with female partner of reproductive potential should use effective contraception
- The mean absolute bioavailability after an oral dose of 125 mg is 46%

Criteria:

- **Criteria for initial therapy:** Ibrance (palbociclib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is an Oncologist
  2. Individual is 18 years of age or older
  3. A confirmed diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer
  4. Used in combination with **EITHER** of the following:
     - Anastrozole or exemestane or letrozole as initial endocrine based therapy in postmenopausal woman
     - Fulvestrant in woman with disease progression following endocrine therapy
  5. **ALL** of the following baseline tests have been completed before initiation of treatment:
     - Complete blood count
     - Comprehensive metabolic panel

  Initial approval duration: 125 mg/day x 28 days for 6 months

- **Criteria for continuation of coverage (renewal request):** Ibrance (palbociclib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by an Oncologist
  2. Individual's cancer has progressed while on therapy
  3. Individual has been adherent with the medication
  4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
     - Significant adverse effect such as:

IBRANCE® (palbociclib) oral capsule (cont.)

- Severe or life-threatening neutropenia or febrile neutropenia

5. There are no significant interacting drugs

Renewal duration: 125 mg/day x 28 days for 6 months

Resources:

Ibrance. Package Insert. Revised by manufacturer 02/2018 Accessed 02-26-2018.

Ibrance. Package Insert. Revised by manufacturer 2/2016 Accessed 03-17-2016, 01-26-16.

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.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.