BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 5/18/17**
SECTION: DRUGS	**LAST REVIEW DATE: 5/16/19**
	LAST CRITERIA REVISION DATE: 5/16/19
	ARCHIVE DATE:

KISQALI® (ribociclib) oral tablet
KISQALI® FEMARA® CO-PACK (ribociclib; letrozole) oral tablets

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.

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.**

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Criteria:

- **Criteria for initial therapy:** Kisqali (ribociclib) 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 **ONE** of the following
     - Recurrent or stage IV (M1) HR-positive, HER2-negative breast cancer with no visceral crisis in a **postmenopausal woman or premenopausal woman** (receiving ovarian suppression or ablation with LHRH agonist) used in combination with an aromatase inhibitor or fulvestrant
     - Recurrent or stage IV (M1) HR-positive, HER2-negative breast cancer and no visceral crisis in **postmenopausal women** treated with prior endocrine therapy within 1 year **or** for **premenopausal women** treated with ovarian ablation/suppression used in combination with tamoxifen (useful in certain circumstances where QT prolongation risk is low)
     - Recurrent or stage IV (M1) (HR)-positive, non-visceral or asymptomatic visceral (HER2)-negative breast cancer in a **male** used in combination with an aromatase inhibitor (anastrozole, letrozole, or exemestane) **or** fulvestrant and used with a drug for suppression of testicular steroidogenesis
     - Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

  4. **ALL** of the following baseline tests have been completed before initiation of treatment:
     - Electrocardiogram (ECG)
     - Comprehensive metabolic panel
     - Complete blood count
     - A negative pregnancy test in a woman of reproductive potential

  Initial approval duration: 63 tabs per 21 days for 6 months

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

  1. Individual continues to be in consultation with an Oncologist

  2. Individual's cancer has not progressed while on therapy

  3. Individual has been adherent with the medication

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4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
   - Significant adverse effect such as:
     - Neutropenia
     - Liver toxicity
     - QTc prolongation associated with torsades de pointes, polymorphic ventricular tachycardia, unexplained syncope, or signs/symptoms of serious arrhythmia

5. There are no significant interacting drugs

Renewal duration: 63 tabs per 21 days for 12 months

Description:

Kisqali (ribociclib) is a kinase inhibitor indicated in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. Aromatase inhibitors include anastrozole, exemestane, or letrozole. Kisqali Femara Co-pack contains ribociclib and letrozole.

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.

Ribociclib is an inhibitor of CDK 4 and CDK 6 enzyme that promotes the growth and spread of cancer cells. These kinases are activated upon binding to D-cyclins and play a crucial role in the signaling pathways which lead to cell cycle progression and cellular proliferation. The cyclin D-CDK4/6 complex regulates cell cycle progression through phosphorylation of the retinoblastoma protein (pRb). Ribociclib decreases pRb phosphorylation leading to arrest in the G1 phase of the cell cycle and reduces cell proliferation in breast cancer cell lines.

Definitions:

QT interval – Fridericia formula

$$QTcF = QT/RR^{0.33}$$

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Resources:

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.

Kisqali (ribociclib). Package Insert. Revised by manufacturer 03/2017. Accessed 03-23-2017, 03-14-2018.

Kisqali (ribociclib). Package Insert. Revised by manufacturer 05/2017. Accessed 04-14-2018.

NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 1.2018, Mar 20, 2018. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

Kisqali (ribociclib) product information accessed 03-21-19 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aaeaef94-f3f5-4367-8ea2-b181d7be2da8

NCCN Compendium: Kisqali (ribociclib) accessed 03-22-19

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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.

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