

# Kisqali (ribociclib succinate)/ Kisqali-Femara Co-pack (ribociclib succinate/letrozole)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Kisqali (ribociclib succinate) tablets Kisqali Femara (ribociclib succinate/letrozole) co-pack	May be subject to quantity limit

## **APPROVAL CRITERIA**

Requests for Kisqali (ribociclib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of advanced, recurrent unresectable, or metastatic breast cancer; **AND**
  - II. Individual has hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/ HER2-) breast cancer;  
**AND**
  - III. Individual meets one of the following:
    - A. Male; **OR**
    - B. Postmenopausal female; **OR**
    - C. Premenopausal treated with ovarian ablation/suppression;**AND**
  - IV. Individual is using in one of the following ways:
    - A. Individual is using as an initial endocrine-based therapy in combination with an aromatase inhibitor (Label, NCCN 1); **OR**
    - B. Individual is using fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy (Label, NCCN 1);
- OR**
- V. Individual has a diagnosis of early breast cancer (Label); **AND**
  - VI. Individual has Stage II or III early breast cancer at a high risk of recurrence; **AND**
  - VII. Individual is HR positive and HER2 negative; **AND**
  - VIII. Individual is using in combination with an aromatase inhibitor for adjuvant treatment;  
**AND**
  - IX. Individual is using for up to 3 years in the absence of disease recurrence or unacceptable toxicity;

**OR**

- X. Individual has a diagnosis of recurrent or metastatic endometrial cancer (NCCN 2A); **AND**
- XI. Individual is using for systemic therapy; **AND**
- XII. Individual is using for ER-positive tumors; **AND**
- XIII. Individual has lower-grade endometroid histologies (for example in those with small tumor volume or an indolent growth pace); **AND**
- XIV. Individual is using in combination with letrozole.

Requests for Kisqali Femara (ribociclib succinate/letrozole) Co-Pack may be approved if the following criteria are met:

- I. Individual is has a diagnosis of advanced, recurrent, or metastatic breast cancer (Label, NCCN 1); **AND**
- II. Individual has hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/ HER2-) breast cancer; **AND**
- III. Individual is using as initial endocrine-based therapy;

**OR**

- IV. Individual has a diagnosis of early breast cancer; **AND**
- V. Individual has Stage II or III early breast cancer at a high risk of recurrence; **AND**
- VI. Individual is HR positive and HER2 negative; **AND**
- VII. Individual is using for adjuvant treatment; **AND**
- VIII. Individual is using for up to 3 years in the absence of disease recurrence or unacceptable toxicity.

Note: Kisqali is taken for 21 consecutive days in a cycle followed by 7 days off treatment. Warnings and precautions include QT interval prolongation, hepatobiliary toxicity, and neutropenia.

**Key References:**

- 1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
- 2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: Updated periodically.
- 3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
- 5. Verzenio (abemaciclib) [prescribing information]. Indianapolis, IN: Lilly USA, LLC; October 2021.
- 6. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 2, 2024.
  - a. Breast Cancer. V2.2024. Revised March 11, 2024.
  - b. Uterine Neoplasms. V2.2024. Revised March 6, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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