

# 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, 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).

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.

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.: 2023. 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.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on March 30, 2021.
  - a. Breast Cancer. V4.2023. Revised March 23, 2023.

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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