MEDICAL MUTUAL®

Drug Policy

Policy:	**Kisqali (ribociclib tablets)** **Kisqali Femara Co-Pack (ribociclib tablets, letrozole tablets)**	**Annual Review Date:** **02/20/2025** **Last Revised Date:** **02/20/2025**

OVERVIEW

Kisqali, a cyclin-dependent kinase (CDK) 4/6 inhibitor, is indicated in combination with an aromatase inhibitor (AI) as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

Kisqali inhibits CDK 4 and 6. These kinases are activated when bound to D-cyclins and play an important role in signaling pathways that lead to cell cycle progression and cellular proliferation. The cyclin D-CDK 4/6 complex regulates cell cycle progression through phosphorylation of the retinoblastoma (Rb) protein. *In vitro*, Kisqali decreases Rb phosphorylation which leads to arrest in the G1 phase (gap phase) of the cell cycle and decreased cell proliferation in breast cancer cell lines. Studies using patient-derived estrogen receptor positive (ER+) breast cancer xenograft models showed the combination of Kisqali and antiestrogens (e.g., letrozole) increased tumor growth inhibition when compared with each of the drugs alone.

Kisqali is available alone, or in a combination package with Femara (letrozole), an aromatase inhibitor.

POLICY STATEMENT

This policy involves the use of Kisqali/Kisqali Femara Co-Pack. Prior authorization is recommended for pharmacy benefit coverage of Kisqali/Kisqali Femara Co-Pack. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Kisqali/Kisqali Femara Co-Pack as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Kisqali/Kisqali Femara Co-Pack be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Kisqali/Kisqali Femara Co-Pack is recommended in those who meet the following criteria:

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1) Breast Cancer in Women

Criteria. *Approve if the patient meets the following criteria:*

- **A.** Patient has recurrent, advanced, or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive-{ER+} and/or progesterone receptor positive {PR+}] disease; AND
- **B.** Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
- **C.** The patient meets ONE of the following criteria (i, ii, iii, or iv):
  - i. The patient is postmenopausal and Kisqali will be used as first-line endocrine therapy in combination with anastrozole, exemestane, letrozole, OR fulvestrant; OR
  - ii. The patient is postmenopausal and Kisqali Femara Co-Pack will be used as first-line endocrine therapy; OR
  - iii. The patient is postmenopausal and Kisqali will be used as second-line or subsequent endocrine therapy in combination with fulvestrant if a CDK4/6 inhibitor has not been used previously; OR
  - iv. The patient is premenopausal or perimenopausal and meets the following conditions (a and b):
    - a. The patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin]), surgical bilateral oophorectomy, or ovarian irradiation; AND
    - b. One of the following (i ii, or iii):
      - i. Kisqali will be used as first-line endocrine therapy in combination with anastrozole, exemestane, letrozole, OR fulvestrant ; OR
      - ii. Kisqali Femara Co-Pack will be used as first-line endocrine therapy; OR
      - iii. Kisqali will be used as second-line or subsequent endocrine therapy in combination with fulvestrant if a CDK4/6 inhibitor has not been used previously

2) Breast Cancer in Men

Criteria. *Approve if the patient meets the following criteria:*

- **A.** Patient has recurrent, advanced, or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive-{ER+} and/or progesterone receptor positive {PR+}] disease; AND
- **B.** Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
- **C.** The patient is receiving concomitant therapy with a gonadotropin-releasing hormone GnRH agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin]) for suppression of testicular steroidogenesis if Kisqali is being used in combination with an aromatase inhibitor; AND
- **D.** One of the following (i ii, or iii):
  - i. Kisqali will be used as first-line endocrine therapy in combination with anastrozole, exemestane, letrozole, OR fulvestrant; OR
  - ii. Kisqali Femara Co-Pack will be used as first-line endocrine therapy; OR
  - iii. Kisqali will be used as second-line or subsequent endocrine therapy in combination with fulvestrant if a CDK4/6 inhibitor has not been used previously

3) Another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation

Criteria. *Prescriber will provide specific diagnosis for documentation. Approve*

4) <u>Patient has been started on Kisqali/Kisqali Femara Co-Pack</u>
Criteria. *Approve for an indication or condition addressed as an approval in this document. Prescriber will provide evidence of beneficial response warranting continuation of therapy.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months
B) *Extended Approval:* 1 year

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Kisqali® tablets [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2022.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 1.2019 – March 14, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 21 March 2023.
3. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Search term: ribociclib. Accessed on 20 February 2025
4. Ribociclib. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 17 February 2025. Accessed on 20 February 2025.