Generic Name: ribociclib

Therapeutic Class or Brand Name: Kisqali

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/8/2025

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

I. Documentation of one of the following diagnoses A through B AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Breast cancer

i. Documentation of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and meets one of the following (1 or 2):

1. Early breast cancer (stage II or stage III)

a. Documentation cancer is at high risk of recurrence by ONE of the following:

i. Any lymph node involvement

ii. Lymph node-negative and ONE of the following:

1. Tumor size greater than 5 cm

2. Tumor size is 2 cm to 5 cm and ONE of the following:

a. Grade 2 disease (and high genomic risk or Ki-67 greater than or equal to 20%)

b. Grade 3 disease

b. Used for adjuvant treatment

c. Used in combination with an aromatase inhibitor (ex: anastrazole, letrozole, or exemestane)

2. Advanced or metastatic breast cancer and meets one of the following (a or b):

a. Used with an aromatase inhibitor (ex: anastrazole, letrozole, exemestane) as initial endocrine-based therapy

b. Used with fulvestrant as an initial endocrine-based therapy or following disease progression on endocrine therapy

Other Uses With Supportive Evidence

B. Endometrial Carcinoma

i. Documentation of recurrent or metastatic disease

ii. Documentation of estrogen receptor (ER)-positive disease

iii. Used in combination with letrozole

II. Minimum age requirement: 18 years old.

III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- The patient has had no prior treatment with a CDK4/6 inhibitor (e.g., Ibrance [palbociclib], Kisqali [ribociclib], or Verzenio [abemaciclib]) resulting in disease progression.

OTHER CRITERIA

- Pre/peri-menopausal women and men treated with the combination of Kisqali plus an aromatase inhibitor or fulvestrant should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Zoladex [goserelin], Lupron [leuprolide], etc.).

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities limited to a 28-day supply
- Early breast cancer
    - Maximum dose: 400 mg (two 200 mg tablets) once daily for 21 consecutive days followed by 7 days off in 28-day treatment cycles.
- Advanced or metastatic breast cancer
    - Maximum dose: 600 mg (three 200 mg tablets) once daily for 21 consecutive days followed by 7 days off in 28-day treatment cycles.

APPROVAL LENGTH

- **Authorization:** 1 year

- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease. Early breast cancer treatment authorized for a maximum duration of 3 years.

APPENDIX

N/A

REFERENCES

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Breast Cancer. Version 4.2025. Updated April 17, 2025. Accessed July 10, 2025. www.nccn.org/professionals/physician_gls/pdf/breast.pdf
2. Kisqali. Prescribing Information. Novartis Pharmaceutical Corporation. September 2024. Accessed July 10, 2025.
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Uterine Neoplasms. Version 3.2025. Updated March 7, 2025. Accessed July 10, 2025. www.nccn.org/professionals/physician_gls/pdf/breast.pdf