

Drug Policy:

Kisqali™ (ribociclib)

POLICY NUMBER UM ONC_1310	SUBJECT Kisqali™ (ribociclib)		DEPT/PROGRAM UM Dept	PAGE 1 of 3
DATES COMMITTEE REVIEWED 04/05/17, 04/11/18, 04/10/19, 12/11/19, 04/08/20, 09/11/20, 08/11/21, 09/08/21, 11/15/21, 05/11/22, 08/10/22, 06/14/23, 07/12/23, 07/10/24, 10/09/24	APPROVAL DATE October 9, 2024	EFFECTIVE DATE October 25, 2024	COMMITTEE APPROVAL DATES 04/05/17, 04/11/18, 04/10/19, 12/11/19, 04/08/20, 09/11/20, 08/11/21, 09/08/21, 11/15/21, 05/11/22, 08/10/22, 06/14/23, 07/12/23, 07/10/24, 10/09/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Kisqali (ribociclib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The requested medication was used within the last year, **AND**
2. The member has not experienced disease progression and/or no intolerance to the requested medication, **AND**
3. Additional medication(s) are not being added to the continuation request.

B. Breast Cancer

1. Kisqali (ribociclib) may be used with an aromatase inhibitor [i.e., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)] for the adjuvant treatment of adult members with ER/PR positive and HER2 negative stage II and III early breast cancer at high risk of recurrence.
 - a. Criteria for high risk of recurrence of breast cancer include any one of following:

- i. Any lymph node involvement (excluding microscopic nodal involvement)
 - ii. If no nodal involvement:
 - 1. Tumor size > 5 cm
 - 2. Tumor size 2 to 5 cm with Grade 2 disease and high genomic risk (Ki67 \geq 20%, an Oncotype DX Breast Recurrence Score of \geq 26, or Prosigna/ PAM50, MammaPrint, or EndoPredict EPclin high-risk scores)
 - 3. Tumor size 2 to 5 cm with Grade 3 disease
- 2. Kisqali (ribociclib) may be used in members with ER/PR positive and HER2 negative recurrent unresectable or metastatic breast cancer as follows:
 - a. In combination with an aromatase inhibitor [i.e., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)] in postmenopausal or premenopausal women treated with ovarian ablation/suppression as first line therapy **OR**
 - b. In combination with Faslodex (fulvestrant) in postmenopausal or premenopausal women treated with ovarian ablation/suppression as subsequent therapy, if CDK4/6 inhibitor [e.g., Ibrance (Palbociclib), Verzenio (abemaciclib)] was not previously used.

III. EXCLUSION CRITERIA

- A. Kisqali (ribociclib) is used after disease progression with the same regimen or disease progression on prior therapy with another CDK4/6 inhibitor, e.g., Ibrance (palbociclib) or Verzenio (abemaciclib).
- B. Concurrent use with cytotoxic chemotherapy.
- C. Dosing exceeds single dose limit of Kisqali (ribociclib) 600 mg.
- D. Treatment exceeds the maximum limit of 63 (200 mg) tablets/month.
- E. Investigational use of Kisqali (ribociclib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
 - 1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
 - 2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
 - 3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
 - 4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
 - 5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
 - 6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. Kisqali prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, NJ 2024.
- B. Slamon DJ, et al. Rationale and trial design of NATALEE: a Phase III trial of adjuvant ribociclib + endocrine therapy *versus* endocrine therapy alone in patients with HR+/HER2- early breast cancer. *Ther Adv Med Oncol*. 2023 May 29;15:17588359231178125. doi: 10.1177/17588359231178125
- C. Clinical Pharmacology Elsevier Gold Standard 2024.
- D. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2024.
- E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.
- F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2024.
- G. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol*. 2014 Apr 20;32(12):1277-80.
- H. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.