UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1215-11
Program	Prior Authorization/Notification
Medication	Kisqali® (ribociclib)
P&T Approval Date	5/2017, 5/2018, 9/2018, 9/2019, 4/2020, 4/2021, 2/2022, 2/2023, 2/2024, 11/2024, 6/2025
Effective Date	8/1/2025

1. Background:

Kisqali (ribociclib) is a kinase inhibitor indicated for the treatment of adult patients with hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)- negative advanced or metastatic cancer in combination with an aromatase inhibitor as initial endocrine-based therapy or fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy. Kisqali is also indicated for use in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence.

The National Comprehensive Cancer Network (NCCN) recommends the use of Kisqali similarly for men and premenopausal women receiving ovarian ablation/suppression with recurrent unresectable (local or regional) or metastatic HR-positive HER2-negative breast cancer disease, in combination with an aromatase inhibitor or Faslodex®(fulvestrant). The use of an aromatase inhibitor in men with breast cancer is ineffective without concomitant suppression of testicular steroidogenesis. The NCCN also recommends Kisqali for estrogen receptor (ER)-positive recurrent or metastatic endometrial carcinoma in combination with letrozole.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Kisqali** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Early-Stage (II or III) Breast Cancer at High Risk of Recurrence</u>

1. <u>Initial Authorization</u>

a. **Kisqali** will be approved based on **all** of the following criteria:

(1) Diagnosis of early-stage (II or III) breast cancer at high risk of recurrence

-AND-

(2) **One** of the following:

(a) Disease is node-positive

-OR-

(b) **Both** of the following:

i. Disease is node-negative

-AND-

ii. **One** of the following:

- Tumor size > 5 cm

-OR-

- **Both** of the following:
  - Tumor size is 2-5 cm

-AND-

  - **One** of the following:
    - Grade 2 and high genomic risk or Ki-67 ≥ 20%
    - Grade 3

-AND-

(3) Disease is hormone receptor (HR)-positive

-AND-

(4) Disease is human epidermal growth factor receptor 2 (HER2)-negative

-AND-

(5) Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Kisqali** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Kisqali therapy

Authorization will be issued for 12 months.

C. Advanced, Recurrent, or Metastatic Breast Cancer

1. Initial Authorization

a. **Kisqali** will be approved based on **all** of the following criteria:

(1) Diagnosis of advanced, recurrent, or metastatic breast cancer

-AND-

(2) Disease is hormone receptor (HR)-positive

-AND-

(3) Disease is human epidermal growth factor receptor 2 (HER2)-negative

-AND-

(4) **One** of the following:

(a) Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)

-OR-

(b) Used in combination with Faslodex (fulvestrant)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Kisqali** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Kisqali therapy

Authorization will be issued for 12 months.

D. Endometrial Carcinoma

1. Initial Authorization

a. **Kisqali** will be approved based on **all** of the following criteria:

(1) Diagnosis of recurrent or metastatic endometrial cancer

-AND-

(2) Tumor is estrogen receptor (ER)-positive

-AND-

(3) Used in combination with letrozole

Authorization will be issued for 12 months.

2. Reauthorization

a. **Kisqali** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Kisqali therapy

Authorization will be issued for 12 months.

E. **NCCN Recommended Regimens**

1. The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Step Therapy and/or Supply limits may be in place.

4. References:

1. Kisqali® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp. September 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed May 2 2025.

Program	Prior Authorization/Notification – Kisqali (ribociclib)
Change Control	
5/2017	New program for Kisqali approved by FDA on 3/13/2017.
5/2018	Annual review. Updated background information and formatting without change to clinical intent.
9/2018	Updated background and criteria to include new indication in combination with fulvestrant.
9/2019	Annual review. Updated background and criteria to align with NCCN recommended use in premenopausal patients in combination with tamoxifen. Added general NCCN recommended review criteria.
4/2020	Updated background and criteria removing use in combination with tamoxifen as it is no longer recommended in NCCN compendium.
4/2021	Annual review without change to clinical intent. Updated references.
2/2022	Updated background and references with no change to clinical criteria.
2/2023	Updated background to align with NCCN recommended use. Added state mandate and updated references with no change to clinical criteria.
2/2024	Annual review. Updated background and added clinical criteria for endometrial carcinoma per NCCN. Updated reference.
11/2024	Annual review. Updated background and clinical criteria for new indication. Updated reference.
6/2025	Updated breast cancer criteria based on NCCN recommendations Separated breast cancer into two separate sections.