

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3108-10
Program	Step Therapy
Medication	Kisqali® (ribociclib)
P&T Approval Date	5/2018, 9/2018, 9/2019, 4/2020, 4/2021, 2/2022, 4/2022, 4/2023, 4/2024, 11/2024
Effective Date	2/15/2025

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try two cyclin-dependent kinase (CDK) 4 and 6 inhibitor before providing coverage for Kisqali®/ Kisqali® Femara® Co-Pack for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

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 Faslodex® (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 with recurrent unresectable (local or regional) or metastatic hormone receptor (HR)-positive HER2-negative breast cancer disease.

Ibrance® (palbociclib) is a kinase inhibitor indicated for the treatment of adult patients with HR-positive HER2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy, or in combination with Faslodex® (fulvestrant) in patients with disease progression following endocrine therapy. The NCCN recommends the use of Ibrance similarly for men with recurrent unresectable (local or regional) or metastatic HR-positive HER2-negative breast cancer disease.

Verzenio® (abemaciclib) is a kinase inhibitor indicated for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy, in combination with Faslodex® (fulvestrant) for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy, as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting, and in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence. The NCCN recommends the use of Verzenio similarly for men with recurrent unresectable (local or regional) or metastatic HR-positive HER2-negative breast cancer disease.

Members currently on Kisqali therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

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,b}:

A. Patients less than 19 years of age

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

- a. Member is less than 19 years of age

Authorization will be issued for 12 months.

B. Breast Cancer

1. **Kisqali** will be approved based on **one** of the following criteria:

- a. **All** of the following:

(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) **Both** of the following:

i. Used in combination with **one** of the following:

- An aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)
- Faslodex (fulvestrant)

-AND-

- ii. Provider attests the patient has a contraindication, history of intolerance, or that the patient is not an appropriate candidate (document reason) to **both** of the following therapies in combination with an aromatase inhibitor (e.g., anastrozole, letrozole):

- Ibrance (palbociclib)
- Verzenio (abemaciclib)

-OR-

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

- i. As continuation of therapy

-AND-

- ii. Patient* has **not** received a manufacturer supplied sample at no cost from a prescriber's office, or any form of assistance from the Novartis sponsored Kisqali Care patient support program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30 day free trial from a pharmacy as a means to establish as a current user of Kisqali

-OR-

- b. **All** of the following:

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

-AND-

- (2) Disease is node-positive

-AND-

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

-AND-

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

-AND-

- (5) **One** of the following:

- (a) Provider attests the patient has a contraindication, history of intolerance, or that the patient is not an appropriate candidate (document reason) to

Verzenio (abemaciclib) in combination with an aromatase inhibitor (e.g., anastrozole, letrozole):

-OR-

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

i. As continuation of therapy

-AND-

ii. Patient* has **not** received a manufacturer supplied sample at no cost from a prescriber's office, or any form of assistance from the Novartis sponsored Kisqali Care patient support program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30 day free trial from a pharmacy as a means to establish as a current user of Kisqali

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Novartis sponsored Kisqali Care patient support program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

C. **Other Indications**

1. **Kisqali** will be approved

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.

^b Coverage of oncology medications may be approved based on state mandates.

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.
- Supply limits and/or Notification may be in place.
- Coverage of oncology medications may be approved based on state mandates.

4. **References:**

1. Kisqali® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp. September 2024.
2. Ibrance tablets [package insert]. New York, NY: Pfizer Labs; September 2023.
3. Ibrance capsules [package insert]. New York, NY: Pfizer Labs; September 2023.
4. Verzenio [package insert]. Indianapolis, IN: Lilly USA, LLC; January 2024.

5. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed October 10, 2024.

Program	Step Therapy - Kisqali (ribociclib)
Change Control	
5/2018	New step therapy criteria.
9/2018	Updated background and criteria to include new Kisqali indication in combination with fulvestrant.
9/2019	Annual review. Updated background and criteria to align with NCCN recommended use of Kisqali in premenopausal patients in combination with tamoxifen. Updated references.
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. Added recurrent to diagnosis criteria. Updated references.
2/2022	Updated background and references with no change to clinical criteria.
4/2022	Updated oncology medications state mandate note.
4/2023	Annual review. Updated background and references with no change to clinical criteria.
4/2024	Annual review. Updated step therapy language with no change to clinical intent. Updated background and references.
11/2024	Annual review. Updated background and clinical criteria for new indication. Updated reference.