

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2020 P 3108-4 |
| Program | Step Therapy |
| Medication | Kisqali® (ribociclib) |
| P&T Approval Date | 5/2018, 9/2018, 9/2019, 4/2020 |
| Effective Date | 7/1/2020; Oxford only: 7/1/2020 |

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 in combination with an aromatase inhibitor as for the treatment of pre/perimenopausal or postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy. Kisqali is also indicated in combination with fulvestrant for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine based therapy or following disease progression on endocrine therapy. The National Comprehensive Cancer Network (NCCN) recommends the use of Kisqali similarly for men with recurrent or metastatic hormone receptor (HR)-positive HER2-negative breast cancer disease.

Ibrance® (palbociclib) is a kinase inhibitor indicated for the treatment of HR-positive HER2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women or men, 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 or metastatic HR-positive HER2-negative breast cancer disease.

Verzenio™ (abemaciclib) is a kinase inhibitor indicated for the treatment of HR-positive HER2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women, in combination with Faslodex® (fulvestrant) for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy, or 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. The NCCN recommends the use of Verzenio similarly for men with recurrent 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 **all** of the following criteria:

- a. Diagnosis of advanced or metastatic breast cancer

-AND-

- b. Disease is hormone-receptor (HR)-positive

-AND-

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

-AND-

- d. **One** of the following:

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

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

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

-OR-

- ii. Used in combination with Faslodex (fulvestrant)

-AND-

- (b) History of failure, contraindication, or intolerance to **both** of the following:

- i. Ibrance (palbociclib)
- ii. Verzenio (abemaciclib)

-OR-

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

- (a) As continuation of therapy

-AND-

- (b) 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 used to treat stage four advanced metastatic cancer

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 used to treat stage IV advanced metastatic cancer may be approved based on state mandates.

4. References:

1. Kisqali® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp. July 2018.
2. Ibrance [package insert]. New York, NY: Pfizer Labs; April 2019.
3. Verzenio [package insert]. Indianapolis, IN: Lilly USA, LLC; June 2019.
4. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 26, 2020.

| Program | Step Therapy - Kisqali (ribociclib) |
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| 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. |