

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 3108-2
Program	Step Therapy
Medication	Kisqali® (ribociclib)
P&T Approval Date	5/2018, 9/2018
Effective Date	12/1/2018; Oxford only: 12/1/2018

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 initial endocrine-based therapy for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy. Kisqali is also indicated 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 hormone receptor (HR)-positive human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women, or in combination with Faslodex® (fulvestrant) in women with disease progression following endocrine therapy. The NCCN recommends the use of Ibrance similarly for men with recurrent or metastatic hormone receptor (HR)-positive HER2-negative breast cancer disease.

Verzenio™ (abemaciclib) is a kinase inhibitor indicated for the treatment of hormone receptor (HR)-positive human epidermal growth factor receptor 2 (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 hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (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 hormone receptor (HR)-positive HER2-negative breast cancer disease.

Members currently on Kisqalitherapy 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) Used in combination with an aromatase inhibitor (e.g. anastrozole, letrozole, exemestane)

-OR-

- (2) Used in combination with Faslodex (fulvestrant)

-AND-

e. **One** of the following:

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

- (a) Ibrance (palbociclib)
(b) 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:

- 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; February 2018.
3. Verzenio [package insert]. Indianapolis, IN: Lilly USA, LLC; February 2018.
4. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed July 30, 2018.

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.