UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3115-3
Program	Step Therapy
Medication	Kisqali® Femara® Co-Pack (ribociclib/letrozole)
P&T Approval Date	9/2018, 9/2019, 9/2020
Effective Date	12/1/2020; Oxford only: 12/1/2020

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® 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 HR-positive, 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. Kisqali® Femara® Co-Pack is a co-packaged product containing Kisqali and letrozole, an aromatase inhibitor, and is indicated as initial endocrine-based therapy for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer. 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. The NCCN also recommends the use of Kisqali in combination with tamoxifen in certain circumstances as a treatment option for first-line therapy with ovarian suppression or ablation for premenopausal patients with HR-positive, HER2-negative metastatic breast cancer. for postmenopausal women treated with prior endocrine therapy within 1 year, or for men with breast cancer.

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 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 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 Femara Co-Pack 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. <u>Patients less than 19 years of age</u>

1. **Kisqali Femara Co-Pack** 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. <u>Breast Cancer</u>

1. **Kisqali Femara Co-Pack** will be approved based on **<u>all</u>** 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) History of failure, contraindication, or intolerance to **both** of the following in combination with an aromatase inhibitor (e.g., anastrozole, letrozole):

(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 Femara Co-Pack** 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® Femara® Co-Pack [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp. July 2020.
2. Kisqali® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp. July 2020.
3. Ibrance [package insert]. New York, NY: Pfizer Labs; November 2019.
4. Verzenio [package insert]. Indianapolis, IN: Lilly USA, LLC; June 2019.
5. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 17, 2020.

Program	Step Therapy – Kisqali Femara Co-Pack (ribociclib/letrozole)
Change Control	
9/2018	New step therapy criteria.
9/2019	Annual review. Updated background without changes to clinical coverage criteria. Updated references.
9/2020	Annual review without changes to clinical coverage criteria. Updated references.