UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 3115-7
Program	Step Therapy
Medication	Kisqali® Femara® Co-Pack (ribociclib/letrozole)
P&T Approval Date	9/2018, 9/2019, 9/2020, 9/2021, 2/2022, 4/2022, 4/2023
Effective Date	7/1/2023; Oxford only: 7/1/2023

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 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 in postmenopausal women or in men 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 adult patients with HR-positive, HER2-negative advanced or metastatic 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 men, or in combination with Faslodex® (fulvestrant) in patients with disease progression following endocrine therapy.

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, 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 and a Ki-67 score ≥20% as determined by an FDA approved test.

The National Comprehensive Cancer Network (NCCN) recommends men with breast cancer be treated similarly to postmenopausal women, except that use of an aromatase inhibitor is ineffective without concomitant suppression of testicular steroidogenesis.

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. Patients less than 19 years of age

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. Breast Cancer

1. **Kisqali Femara Co-Pack** 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) 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):

      (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 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® Femara® Co-Pack [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp. October 2022.
2. Kisqali® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp. October 2022
3. Ibrance® tablets [package insert]. New York, NY: Pfizer Labs; December 2022.
4. Ibrance® capsules [package insert]. New York, NY: Pfizer Labs; December 2022.
5. Verzenio® [package insert]. Indianapolis, IN: Lilly USA, LLC; October 2021.
6. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed March 2, 2022.

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.
9/2021	Annual review. Updated background. Updated step criteria language with no change to clinical intent. References updated.
2/2022	Updated background and references with no change to clinical criteria.
4/2022	Added oncology medications state mandate note.
4/2023	Annual review. Updated references.