UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Kisqali Femara Co-Pack

Program	Prior Authorization
Medication	Kisqali® Femara® Co-Pack (ribociclib/letrozole)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2018
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

1. Background:

Kisqali® Femara® Co-Pack is a co-packaged product containing ribociclib, a kinase inhibitor, and letrozole, an aromatase inhibitor, and is indicated 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. 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.

2. Coverage Criteria:

A. Breast Cancer

1. **Initial Authorization**

   a. **Kisqali Femara Co-Pack** will be approved based on **all** of the following criteria:

      (1) Diagnosis of advanced 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) History of failure, contraindication, or intolerance to Verzenio (abemaciclib) plus an aromatase inhibitor (e.g., anastrozole, letrozole)

-OR-

(b) Patient is currently on Kisqali Femara Co-Pack therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. **Kisqali Femara Co-Pack** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Kisqali Femara Co-Pack therapy

Authorization will be issued for 12 months.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Kisqali Femara Co-Pack** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Kisqali Femara Co-Pack** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Kisqali Femara Co-Pack therapy

Authorization will be issued for 12 months.

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 may be in place.

4. References:

1. Kisqali® Femara® Co-Pack [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp. February 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 2019.

Program	Prior Authorization
Change Control	
Date	Change
9/2018	New program.
9/2019	Annual review. Updated background and references.
9/2020	Annual review. Minor change to background. Updated references. Added Additional Clinical Rules section.