UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Kisqali

Program	Prior Authorization
Medication	Kisqali® (ribociclib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	5/2017
Pharmacy and Therapeutics Approval Date	4/2020
Effective Date	6/2020

1. Background:

Kisqali (ribociclib) is a kinase inhibitor indicated in combination with an aromatase inhibitor for the treatment of pre/perimenopaual 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 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 and premenopausal women receiving ovarian ablation/suppression with recurrent or metastatic HR-positive, HER2-negative breast cancer disease, in combination with an aromatase inhibitor or Faslodex. The use of an aromatase inhibitor in men with breast cancer is ineffective without concomitant suppression of testicular steroidogenesis.

2. Coverage Criteria:

A. <u>Breast Cancer</u>

1. <u>Initial Authorization</u>

a. **Kisqali** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of advanced, recurrent, or metastatic breast cancer

-AND-

(2) **<u>Both</u>** of the following:

(a) Disease is hormone receptor (HR)-positive
(b) Disease is human epidermal growth factor receptor 2 (HER2)-negative

-AND-

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

i. **One** of the following:

a. Used in combination with an aromatase inhibitor [e.g., Femara (letrozole)]

-OR-

b. Used in combination with Faslodex (fulvestrant)

-AND-

ii. **One** of the following:

a. History of failure, contraindication, or intolerance to Verzenio (abemaciclib)

-OR-

b. Patient is currently on Kisqali therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. **Kisqali** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Kisqali therapy

Authorization will be issued for 12 months.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Kisqali** 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** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Kisqali 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® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp. July 2018.
2. The NCCN Drugs and Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content.asp. Accessed February 26, 2020.

Program	Prior Authorization –Kisqali (ribociclib)
Change Control	
Date	Change
5/2017	New program. FDA-approved on 3/13/2017.
4/2018	Added step therapy criteria through trial of both Verzenio and Ibrance or allow continuation of Kisqali therapy. Added NCCN Recommended review criteria. Updated references.
6/2018	Removed Ibrance as a step therapy medication
9/2018	Updated background and criteria to include new Kisqali indication in combination with fulvestrant. Updated references.
9/2019	Updated background and criteria align with NCCN guidance. Updated references.
4/2020	Removed use in combination with tamoxifen since it is no longer

	NCCN recommended. Updated background and references.