

### Clinical Pharmacy Program Guidelines for Kisqali

Program	Prior Authorization
Medication	Kisqali® (ribociclib)
Issue Date	5/2017
Pharmacy and Therapeutics Approval Date	5/2017
Effective Date	7/2017

**1. Background:**

Kisqali (ribociclib) is a kinase inhibitor indicated in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

**2. Coverage Criteria:**

<p><b>A. <u>Breast Cancer</u></b></p> <p><b>1. <u>Initial Authorization</u></b></p> <p>a. <b>Kisqali</b> will be approved based on <b>all</b> of the following criteria:</p> <p>(1) Diagnosis of advanced or metastatic breast cancer</p> <p style="text-align: center;"><b>-AND-</b></p> <p>(2) <b>Both</b> of the following:</p> <p>(a) Disease is hormone receptor (HR)-positive</p> <p>(b) Disease is human epidermal growth factor receptor 2 (HER2)-negative</p> <p style="text-align: center;"><b>-AND-</b></p> <p>(3) Used in combination with an aromatase inhibitor [e.g., Femara (letrozole)].</p> <p><b>Authorization will be issued for 12 months.</b></p>
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**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.**

**3. References:**

1. Kisqali<sup>®</sup> [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp. March 2017.

Program	Prior Authorization –Kisqali (ribociclib)
<b>Change Control</b>	
Date	Change
5/2017	New program. FDA-approved on 3/13/2017.