

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## Kisqali (ribociclib succinate)/Kisqali-Femara (ribociclib succinate/letrozole)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Kisqali (ribociclib succinate) tablets Kisqali Femara (ribociclib succinate/letrozole) co-pack	May be subject to quantity limit

### APPROVAL CRITERIA

Requests for Kisqali(ribociclib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of advanced or metastatic breast cancer (NCCN 1); **AND**
- II. Individual has hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/ HER2-) breast cancer;

**AND**

- III. Individual is using Kisqali (ribociclib) as an initial endocrine-based therapy in combination with an aromatase inhibitor or tamoxifen (NCCN 1);
- OR**
- IV. Individual is postmenopausal using as initial endocrine-based therapy or following disease progression on endocrine therapy in combination with fulvestrant.

Requests for Kisqali Femara (ribociclib succinate/letrozole) Co-Pack may be approved if the following criteria are met:

- I. Individual is has a diagnosis of advanced or metastatic breast cancer (NCCN 1); **AND**
- II. Individual has hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/ HER2-) breast cancer.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Note: Kisqali is taken for 21 consecutive days in a cycle followed by 7 days off treatment. Warnings and precautions include QT interval prolongation, hepatobiliary toxicity, and neutropenia.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: August 31, 2018.

DrugPoints® System [Internet Database]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

The NCCN Drugs & Biologics Compendium (NCCN Compendium™) © 2018 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.

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