

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Kisqali (ribociclib succinate)/ Kisqali-Femara Co-pack (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 as an initial endocrine-based therapy in combination with an aromatase inhibitor or tamoxifen (NCCN 1);
- OR**
- IV. Individual is 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 (Label, 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.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

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:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 25, 2019
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 25, 2019.
 - a. Breast Cancer. V2.2019. Revised July 2, 2019.
 - b. Soft Tissue Sarcoma. V2.2019. Revised February 4, 2019.

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