PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**KISQALI**
(generic)	**(ribociclib)**
BRAND NAME	**KISQALI FEMARA CO-PACK**
(generic)	**(ribociclib and letrozole)**
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref #1638-A***

FDA-APPROVED INDICATION

Kisqali is 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.[1]

The Kisqali Femara Co-Pack is indicated 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]

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of breast cancer? [If no, no further questions.]	Yes	No
2	Is the disease advanced or metastatic? [If no, no further questions.]	Yes	No
3	Does the patient have hormone receptor (HR)-positive breast cancer? [If no, no further questions.]	Yes	No
4	Does the patient have human epidermal growth factor receptor 2 (HER2)-negative breast cancer? [If no, no further question.]	Yes	No
5	Is the patient postmenopausal? [If no, no further questions.]	Yes	No
6	Is the prescribed drug Kisqali Femara Co-Pack? [If yes, no further questions.]	Yes	No
7	Will the drug be used in combination with an aromatase inhibitor (eg, letrozole)?	Yes	No

Guidelines for Approval			
Duration of Approval: 12 months			
Set 1: Kisqali		**Set 2:** Kisqali Femara Co-Pack	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	6	1	None
2		2	
3		3	

4		4	
5		5	
7		6	

Mapping Instructions		
	Yes	**No**
1	Go to 2	Deny
2	Go to 3	Deny
3	Go to 4	Deny
4	Go to 5	Deny
5	Go to 6	Deny
6	Approve, 12 months	Go to 7
7	Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCE

1. Kisqali [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2017.
2. Kisqali Femara Co-Pack [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2017.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (ST) 03/2017
Revised:	ST 06/2017 (added Co-Pack), 07/2017 (CMS)
Reviewed:	CDPR/JG 03/2017, GAD 06/2017
External Review:	03/2017