Kisqali® (ribociclib)
(Oral)

Document Number: IC-0294

Last Review Date: 08/04/2020
Date of Origin: 04/25/2017
Dates Reviewed: 04/2017, 04/2018, 08/2018, 08/2019, 08/2020

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Kisqali 200 mg tablet: 1 container per 28 days
- Kisqali Femara Co-Pack Cartons: 1 carton per 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 600 mg daily for 21 days in a 28-day cycle

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Baseline ECG indicates QTcF is less than 450 msec; **AND**

Universal Criteria [1]

- Patient has not received previous therapy with a cyclin-dependent kinase (CDK) 4 and 6 inhibitor (e.g., palbociclib, abemaciclib, etc.); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Patient will avoid concomitant use with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Patient will avoid concomitant use with strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin, nefazodone, grapefruit, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

– Patient will avoid concomitant use with drugs that prolong QT (e.g., amiodarone, quinidine, sotalol, etc.) and the QT interval (e.g., clarithromycin, haloperidol, methadone, etc.); **AND**

Breast Cancer † [1-7]

- Patient has hormone receptor (HR)-positive disease; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
- Patient has advanced, recurrent, or metastatic disease; **AND**
- Patient does not have visceral crisis; **AND**
  - Patient is a male and receiving androgen deprivation therapy (ADT); **OR**
  - Patient is a postmenopausal woman; **OR**
  - Patient is a pre/peri-menopausal woman receiving ovarian ablation/suppression (e.g., surgical ablation, suppression with a gonadotropin-releasing hormone agonist, etc.); **AND**
- Therapy is being used as one of the following:
  - As initial endocrine based therapy in combination with an aromatase inhibitor (e.g., letrozole); **OR**
  - Used in combination with fulvestrant as initial endocrine based therapy OR as subsequent therapy after disease progression on or after endocrine therapy

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria [1-7]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria identified in Section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: QT interval prolongation, hepatobiliary toxicity, neutropenia, severe interstitial lung disease/pneumonitis, severe cutaneous adverse reactions [i.e. Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), drug-induced hypersensitivity syndrome (DiHS), drug reaction with eosinophilia and systemic symptoms (DRESS)], etc.; **AND**
  - QTcF interval is not > 500 msec; **OR**
  - QTcF interval has not had a > 60 msec change from baseline along with any of the following: Torsades de Pointes, polymorphic ventricular tachycardia, unexplained syncope, or signs/symptoms of serious arrhythmia

V. Dosage/Administration [1]

Indication	Dose
Breast Cancer	600 mg (three 200 mg tablets) orally once daily for 21 consecutive days followed by 7 days off in a 28-day cycle. • Co-administer with an aromatase inhibitor or fulvestrant (*refer to the full prescribing information for the recommended doses*).

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

NDC:

- KISQALI 200 mg tablet:
  - 600 mg daily dose; container of 3 blister packs of 21 tablets each: 00078-0874-xx
  - 400 mg daily dose; container of 3 blister packs of 14 tablets each: 00078-0867-xx
  - 200 mg daily dose; container of 1 blister pack of 21 tablets: 00078-0860-xx
- KISQALI FEMARA CO-PACK Cartons:
  - 3 Blister packs, containing 21 tablets (200 mg per tablet) (600 mg daily dose) of Kisqali plus one 28-tablet count bottle of Femara: 00078-0923-xx
  - 3 Blister packs, containing 14 tablets (200 mg per tablet) (400 mg daily dose) of Kisqali plus one 28-tablet count bottle of Femara: 00078-0916-xx
  - 1 Blister pack, containing 21 tablets (200 mg per tablet) (200 mg daily dose) of Kisqali plus one 28-tablet count bottle of Femara: 0 0078-0909-xx

VII. References

1. Kisqali [package insert]. East Hanover, NJ; Novartis; July 2020. Accessed July 2020.
2. Kisqali Femara Co-Pack [package insert]. East Hanover, NJ; Novartis; July 2020. Accessed July 2020.
3. Hortobagyi GN, Stemmer SM, Burris HA, et al. Ribociclib as First-Line Therapy for HR-Positive, Advanced Breast Cancer. N Engl J Med. 2016 Nov 3;375(18):1738-1748.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) ribociclib. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2020.
5. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer 4.2020. National Comprehensive Cancer Network,

2020. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2020.

6. Tripathy D, Im SA, Colleoni M, et al. Ribociclib Plus Endocrine Therapy for Premenopausal Women With Hormone-Receptor-Positive, Advanced Breast Cancer (MONALEESA-7): A Randomised Phase 3 Trial. Lancet Oncol 2018 Jul;19(7):904-915. doi: 10.1016/S1470-2045(18)30292-4. Epub 2018 May 24.
7. Slamon D, Neven P, Chia S, et al. Phase III Randomized Study of Ribociclib and Fulvestrant in Hormone Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative Advanced Breast Cancer: MONALEESA-3. J Clin Oncol 2018 Aug 20;36(24):2465-2472. doi: 10.1200/JCO.2018.78.9909. Epub 2018 Jun 3.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast

ICD-10	ICD-10 Description
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
Z85.3	Personal history of malignant neoplasm of breast

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC