KISQALI

ACCESS SUPPORT GUIDE

CLINICAL CONSIDERATIONS

Understand clinical trial results to communicate the appropriate indication for KISQALI® (ribociclib) and the treatment goal for each patient to health plans

Review the Clinical Considerations for KISQALI

COVERAGE REQUEST

Simplify the insurance coverage process for KISQALI by including information health plans want to know

Checklist
Sample Letter of Appeal
Sample Letter of Medical Necessity

ELIGIBLE FINANCIAL RESOURCES

Novartis Patient Support™ offers a range of savings options to help KISQALI patients access treatment

Download the Co-Pay Plus card here

Novartis cannot guarantee insurance coverage or reimbursement for any patient. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider (HCP) to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Please click here for Important Safety Information, and click here for full Prescribing Information for KISQALI.

NOVARTIS

KISQALI® ribociclib 200 mg tablets

The indications and clinical trial results in this resource can help support access to KISQALI® (ribociclib) as an appropriate treatment choice

It is important to identify the appropriate indication for adult patients.

mBC

KISQALI in combination with an AI[1]:

- KISQALI is indicated for the treatment of adults with HR+/HER2- aBC or mBC in combination with an AI as initial endocrine-based therapy

KISQALI in combination with fulvestrant[1]:

- KISQALI is indicated for the treatment of adults with HR+/HER2- aBC or mBC in combination with fulvestrant as initial endocrine-based therapy or following disease progression on ET

eBC

KISQALI in combination with an AI[1]:

- KISQALI is indicated in combination with an AI for the adjuvant treatment of adults with HR+/HER2- stage II and III eBC at high risk of recurrence

NATIONAL COMPREHENSIVE CANCER NETWORK® (NCCN®) CATEGORY 1 RECOMMENDATION

NCCN differentiates ribociclib (KISQALI®) as the first and only NCCN Category 1 Preferred treatment option when used in combination with an AI for appropriate patients with HR+/HER2- mBC in 1L and for appropriate patients with HR+/HER2- eBC, including those with high-risk, node-negative disease[2]

NATALEE: At a median follow-up of 33.3 months, iDFS (primary end point) at the 3-year landmark was 90.7% for KISQALI + NSAI vs 87.6% for NSAI alone **(absolute difference 3.1%);** there was a 25.1% relative reduction in the risk of an iDFS event; HR=0.749 (95% CI: 0.628-0.892).[1,3,4]

MONALEESA-2, statistically significant OS in 1L postmenopausal patients: At a median follow-up of 80 months, mOS was 63.9 months with KISQALI + letrozole (95% CI: 52.4-71.0) vs 51.4 months with letrozole (95% CI: 47.2-59.7); HR=0.765 (95% CI: 0.628-0.932); *P*=.004. OS was a secondary end point; PFS was the primary end point.[1,5,6]

In HR+/HER2- eBC, high-risk node-negative disease is defined as either tumor size >5 cm, or if tumor size 2-5 cm, either grade 2 (with high genomic risk or Ki-67 ≥20%), or grade 3.[1,2]

There is controversy on the choice of CDK4/6i as there are no head-to-head comparisons between the agents, and there are some differences in the study populations in the phase III randomized studies.

NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

1L, first-line; aBC, advanced breast cancer; AI, aromatase inhibitor; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; CI, confidence interval; eBC, early breast cancer; ET, endocrine therapy; HER2-, human epidermal growth factor receptor 2–negative; HR, hazard ratio; HR+, hormone receptor–positive; iDFS, invasive disease-free survival; mBC, metastatic breast cancer; mOS, median overall survival; NCCN, National Comprehensive Cancer Network; NSAI, nonsteroidal aromatase inhibitor; OS, overall survival; PFS, progression-free survival.

IMPORTANT SAFETY INFORMATION

Interstitial lung disease/pneumonitis. Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with KISQALI and other CDK4/6 inhibitors.

In patients with eBC (NATALEE) who received 400 mg KISQALI plus a nonsteroidal aromatase inhibitor (NSAI), 1.5% of patients had ILD/pneumonitis (grade 1/2).

Please click here for Important Safety Information, and click here for full Prescribing Information for KISQALI.

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Select clinical trial results for KISQALI® (ribociclib)

MONALEESA-2: KISQALI + letrozole, postmenopausal | MONALEESA-3: KISQALI + fulvestrant, postmenopausal | MONALEESA-7: KISQALI + NSAI + goserelin, premenopausal | NATALEE: KISQALI + NSAI in stage II and III eBC

MONALEESA-2: Postmenopausal women, in combination with letrozole, as a 1L therapy[1,5-8]

Clinical study description	**MONALEESA-2** was a randomized, double-blind, placebo-controlled phase III study of KISQALI (600 mg once daily; 3 weeks on, 1 week off) + letrozole (n=334) or placebo + letrozole (n=334), until disease progression or unacceptable toxicity occurred, in postmenpausal patients with HR+/HER2- mBC who received no prior therapy for advanced disease. OS was a secondary end point; PFS was the primary end point.
PFS (primary end point)	For patients receiving KISQALI + letrozole, at a median follow-up of 15 months, mPFS was not reached with KISQALI + letrozole (95% CI: 19.3-NR) vs 14.7 months with placebo + letrozole (95% CI: 13.0-16.5); HR=0.556 (95% CI: 0.429-0.720); *P*<.0001.
OS	For patients receiving KISQALI + letrozole, at a median follow-up of 80 months, the mOS was 63.9 months (95% CI: 52.4-71.0) vs 51.4 months among those receiving placebo + letrozole (95% CI: 47.2-59.7). There was a 24% reduction in risk of death with KISQALI + letrozole with an HR of 0.765 (95% CI: 0.628-0.932); *P*=.004.
Safety profile	The most common (≥20% on the KISQALI arm and ≥2% higher than placebo) ARs, including laboratory abnormalities, were neutrophils decreased, leukocytes decreased, hemoglobin decreased, nausea, lymphocytes decreased, alanine aminotransferase increased, aspartate aminotransferase increased, fatigue, diarrhea, alopecia, vomiting, platelets decreased, constipation, headache, and back pain.

OS BENEFIT WITH KISQALI INCREASED OVER TIME[6] At 6 years, the survival rate of patients receiving KISQALI + letrozole was 44% vs 32% with placebo + letrozole.

KISQALI is the only CDK4/6i to demonstrate a statistically significant OS advantage vs placebo in 1L postmenopausal patients with an AI[1,9,10]

AR, adverse reaction; mPFS, median progression-free survival; NR, not reached.

IMPORTANT SAFETY INFORMATION (continued)
Interstitial lung disease/pneumonitis (continued). In patients with advanced or mBC (MONALEESA-2, MONALEESA-3, MONALEESA-7), 1.6% of patients had ILD/pneumonitis of any grade, 0.4% had grade 3/4, and 0.1% had a fatal outcome. Additional cases of ILD/pneumonitis have occurred in the postmarketing setting, some resulting in death.

Please click here for Important Safety Information, and click here for full Prescribing Information for KISQALI.

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Select clinical trial results for KISQALI® (ribociclib)

MONALEESA-2: KISQALI + letrozole, postmenopausal | MONALEESA-3: KISQALI + fulvestrant, postmenopausal | MONALEESA-7: KISQALI + NSAI + goserelin, premenopausal | NATALEE: KISQALI + NSAI in stage II and III eBC

MONALEESA-3: Postmenopausal women, in combination with fulvestrant, as a 1L therapy for advanced disease or a 2L therapy after progression on ET[1,11,12]

Clinical study description	**MONALEESA-3** was a randomized, double-blind, placebo-controlled phase III study of KISQALI (600 mg once daily; 3 weeks on, 1 week off) + fulvestrant (n=484) or placebo + fulvestrant (n=242), until disease progression or unacceptable toxicity occurred, in postmenopausal patients with HR+/HER2- mBC who have received no or only 1 line of prior ET for advanced disease. OS was a secondary end point; PFS was the primary end point.
PFS (primary end point)	In the primary analysis at a median follow-up of 20 months, KISQALI significantly improved PFS in the clinical study, with 20.5 months mPFS (95% CI: 18.5-23.5) with KISQALI + fulvestrant vs 12.8 months (95% CI: 10.9-16.3) with fulvestrant (HR=0.593 [95% CI: 0.480-0.732]; *P*<.0001).
OS	At a median follow-up of 39 months, mOS with KISQALI + fulvestrant was not reached (95% CI: 42.5-NR) vs 40.0 months with placebo + fulvestrant (95% CI: 37.0-NR); *P*=.00455 (HR=0.724 [95% CI: 0.568-0.924]).
Safety profile	The most common (≥20% on the KISQALI arm and ≥2% higher than placebo) ARs, including laboratory abnormalities, were leukocytes decreased, neutrophils decreased, lymphocytes decreased, creatinine increased, hemoglobin decreased, gamma-glutamyl transferase increased, aspartate aminotransferase increased, nausea, alanine aminotransferase increased, infections, platelets decreased, diarrhea, vomiting, constipation, glucose serum decreased, cough, rash, and pruritus.

KISQALI demonstrated a statistically significant OS advantage in 1L and 2L postmenopausal patients with fulvestrant vs placebo + fulvestrant[1]

2L, second-line.

IMPORTANT SAFETY INFORMATION (continued)
Interstitial lung disease/pneumonitis (continued). Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis, which may include hypoxia, cough, and dyspnea. In patients who have new or worsening respiratory symptoms suspected to be due to ILD or pneumonitis, interrupt KISQALI immediately and evaluate the patient. Permanently discontinue treatment with KISQALI in patients with severe ILD/pneumonitis or any recurrent symptomatic ILD/pneumonitis.

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Select clinical trial results for KISQALI® (ribociclib)

MONALEESA-7: Premenopausal women, in combination with an NSAI and goserelin, as a 1L therapy[1,13-15]

Clinical study description	**MONALEESA-7** was a randomized, double-blind, placebo-controlled phase III study of KISQALI (600 mg once daily; 3 weeks on, 1 week off) + NSAI or tamoxifen + goserelin (n=335) or placebo + NSAI or tamoxifen + goserelin (n=337), until disease progression or unacceptable toxicity occurred, in premenopausal patients with HR+/HER2- mBC who received no prior ET for advanced disease. **KISQALI is not indicated for concomitant use with tamoxifen**. Efficacy results are from a prespecified subgroup analysis of 495 patients who received KISQALI (n=248) or placebo (n=247) with an NSAI + goserelin. OS was a secondary end point; PFS was the primary end point.
PFS (primary end point)	At a median follow-up of 19 months, KISQALI achieved 27.5 mPFS (95% CI: 19.1-NR) with KISQALI + NSAI + goserelin vs 13.8 months (95% CI: 12.6-17.4) with placebo + NSAI + goserelin (HR=0.569 [95% CI: 0.436-0.743]).
OS	KISQALI significantly improved OS for pre/perimenopausal women in the MONALEESA-7 clinical trial. At a median follow-up of 35 months, mOS was NR (95% CI: NR, NR) with KISQALI + NSAI + goserelin vs 40.7 (95% CI: 37.4, NR) with placebo + NSAI + goserelin; HR=0.699 (95% CI: 0.501, 0.976).
Safety profile	The most common (≥20% on the KISQALI arm and ≥2% higher than placebo) ARs, including laboratory abnormalities, were leukocytes decreased, neutrophils decreased, hemoglobin decreased, lymphocytes decreased, gamma-glutamyl transferase increased, aspartate aminotransferase increased, infections, arthralgia, alanine aminotransferase increased, nausea, platelets decreased, and alopecia.

MONALEESA-7 is the only CDK4/6i trial dedicated to premenopausal patients[1,14,16]

*Results should be interpreted with caution as there was no control for type-error.

IMPORTANT SAFETY INFORMATION (continued)
Severe cutaneous adverse reactions. Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug-induced hypersensitivity syndrome (DiHS)/drug reaction with eosinophilia and systemic symptoms (DRESS) can occur in patients treated with KISQALI.

Please click here for Important Safety Information, and click here for full Prescribing Information for KISQALI.

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Select clinical trial results for KISQALI® (ribociclib)

MONALEESA-2: KISQALI + letrozole, postmenopausal | MONALEESA-3: KISQALI + fulvestrant, postmenopausal | MONALEESA-7: KISQALI + NSAI + goserelin, premenopausal | NATALEE: KISQALI + NSAI in stage II and III eBC

NATALEE: Adults with HR+/HER2- stage II and III eBC at high risk of recurrence[1,3,4,17]

Clinical study description	**NATALEE** was a randomized, multicenter, open-label, phase III study of KISQALI 400 mg (dosed orally, once daily for the first 21 days followed by 7 days off, resulting in a complete cycle of 28 days) + letrozole or anastrozole (n=2549) vs letrozole or anastrozole alone (n=2552) for the adjuvant treatment of men and women with stage II/III HR+/HER2- eBC, including all those with node-positive or high-risk node-negative disease (eligible stages and nodal status include: anatomic stage group IIB-III, or anatomic stage group IIA that is either node positive, or node negative with histologic grade 3, or histologic grade 2 with Ki-67 ≥20% and/or high risk by gene signature testing).
iDFS (primary end point)*	At a median follow-up of 33.3 months, with 509 iDFS (primary end point) events in the study (226 [8.9%] in the KISQALI arm and 283 [11.1%] in the NSAI-alone arm), iDFS at the 3-year landmark was 90.7% for KISQALI + NSAI vs 87.6% for NSAI alone **(absolute difference 3.1%);** there was a 25.1% relative reduction in the risk of an iDFS event; HR=0.749 (95% CI: 0.628-0.892).
Safety profile	The most common ARs, including laboratory abnormalities occurring in at least 20% of patients treated with KISQALI, were lymphocytes decreased, leukocytes decreased, neutrophils decreased, hemoglobin decreased, ALT increased, AST increased, infections, creatinine increased, platelets decreased, nausea, headache, and fatigue.

ALT, alanine aminotransferase; AST, aspartate aminotransferase; DDFS, distant disease-free survival.
*Results from the 4-year analysis were not prespecified and were observational in nature; as such, there was no prespecified statistical procedure controlling for type 1 error.

IMPORTANT SAFETY INFORMATION (continued)
Severe cutaneous adverse reactions (continued). If signs or symptoms of SCARs occur, interrupt KISQALI until the etiology of the reaction has been determined. Early consultation with a dermatologist is recommended to ensure greater diagnostic accuracy and appropriate management.

Please click here for Important Safety Information, and click here for full Prescribing Information for KISQALI.

KISQALI® ribociclib 200 mg tablets

The tools provided in this section can help you navigate the coverage process and documentation commonly requested by health plans

Each health plan manages access to KISQALI® (ribociclib) differently. Checklists and sample letters on the following pages can help you provide the information needed to facilitate approval.

Provide contact details

Provide contact information and describe the type of coverage requested.

- **Prescribing physician**, including National Provider Identifier (NPI) #, and fax and phone numbers
- **Patient**, including policy and group numbers, date of birth, and phone number

Also included in this section are sample letters to be used if the health plan requires further documentation to support the prescribing physician's clinical decision.

Novartis cannot provide any assistance to your office in completing or submitting forms or letters related to coverage requests.

Describe the patient's breast cancer diagnosis and current health status

The health plan will need to understand what makes this patient an appropriate candidate for treatment with KISQALI.

Information that may support the appropriateness of KISQALI may include:

- ☐ Breast cancer diagnosis, including relevant ICD-10 code(s)

> Click here for a list of common ICD-10 codes for male and female breast cancer

- ☐ Stage of disease
- ☐ Menopausal status (if female)
- ☐ Documentation that the patient's breast cancer is HR+/HER2-
- ☐ Relevant medical records, such as clinic notes, should be provided as attachments and may need to be pulled from past dates to capture the relevant information
- ☐ Communicate the unique benefit of KISQALI for the patient (see next page)
- ☐ If available, you may also wish to send laboratory work and/or imaging results
- ☐ If the patient is already taking KISQALI, consider including information about the patient's breast cancer symptoms at the time KISQALI was first prescribed and any changes in symptoms since treatment began
- ☐ Indicate whether the patient has been treated with previous therapy for breast cancer and list all previous therapies along with length of treatment

ICD-10, International Classification of Diseases, 10th Revision.

IMPORTANT SAFETY INFORMATION (continued)
Severe cutaneous adverse reactions (continued). If SJS, TEN, or DiHS/DRESS is confirmed, permanently discontinue KISQALI. Do not reintroduce KISQALI in patients who have experienced SCARs or other life-threatening cutaneous reactions during KISQALI treatment.

Please click here for Important Safety Information, and click here for full Prescribing Information for KISQALI.

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Communicate the clinical results of KISQALI® (ribociclib)

The indication and other clinical information can help provide a clinical rationale for the choice of KISQALI.

Communicate the indication

It is important to communicate the indication for which KISQALI is being prescribed.[1]

KISQALI is indicated in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer (eBC) at high risk of recurrence.

KISQALI is indicated for the treatment of adults with HR-positive, HER2-negative advanced or metastatic breast cancer in combination with:

- an aromatase inhibitor as initial endocrine-based therapy; or
- fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy.

Provide clinical data in support of the prescriber's recommendation

KISQALI—proven OS benefit across all 3 phase III trials[1,18]

☐ In postmenopausal women with HR+/HER2- mBC, in combination with letrozole, as a 1L therapy:
- Median OS was 63.9 months with KISQALI + letrozole (95% CI: 52.4–71.0) vs 51.4 months with letrozole (95% CI: 47.2–59.7); HR=0.765 (95% CI: 0.628–0.932); *P*=0.004[1]

Click here for MONALEESA-2 data

☐ In postmenopausal women with HR+/HER2- mBC, in combination with fulvestrant, as a 1L therapy for advanced disease or as a 2L therapy after progression on ET[1]:
- Median OS was NR (95% CI: 42.5, NR) with KISQALI + fulvestrant vs 40.0 (95% CI: 37.0, NR) placebo + fulvestrant; HR=0.724 (95% CI: 0.568–0.924); *P*=0.00455[1]

Click here for MONALEESA-3 data

☐ In premenopausal women with HR+/HER2- mBC, in combination with an NSAI and goserelin, as a 1L therapy[1]:
- Median OS was NR (95% CI: NR, NR) with KISQALI + NSAI + goserelin vs 40.7 (95% CI: 37, 4, NR) with placebo + NSAI + goserelin; HR=0.699 (0.501, 0.976)[1]

Click here for MONALEESA-7 data

KISQALI—a proven risk reduction in invasive for patients with stage II and III HR+/HER2- eBC at high risk of recurrence via phase III trial[3]

☐ In adults with HR+/HER2- stage II and III eBC in combination with an NSAI:
- iDFS at the 3-year landmark was 90.7% for KISQALI + NSAI vs 87.6% for NSAI alone; HR=0.749 (95% CI: 0.628–0.892)

Click here for NATALEE data

Clinical trial results may be useful in communicating about KISQALI to health plans.
Reminder: KISQALI is not indicated for concomitant use with tamoxifen[1]

IMPORTANT SAFETY INFORMATION (continued)
QT interval prolongation. KISQALI has been shown to prolong the QT interval in a concentration-dependent manner.

Please click here for Important Safety Information, and click here for full Prescribing Information for KISQALI.

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Provide information from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer that support the choice of ribociclib (KISQALI®)

Consider citing the most current NCCN Guidelines® for Breast Cancer

NCCN differentiates ribociclib (KISQALI) as the first and only Category 1 Preferred treatment option when used in combination with an AI for appropriate patients with HR+/HER2- mBC in 1L and for appropriate patients with HR+/HER2- eBC, including those with high-risk, node-negative disease[2]

Click here to access current NCCN Guidelines for Breast Cancer

Note: NCCN Guidelines are available to registered users. New users can **click here** to register for a free account.

Stage II or III postmenopausal or premenopausal patients with any node-positive or high-risk, node-negative

- HR+/HER2- eBC
- AI + CDK4/6i
- Ribociclib is a Category 1 Preferred option in combination with an AI for 1L patients

Postmenopausal or premenopausal patients receiving ovarian ablation or suppression[2]

HR+/HER2- aBC or mBC

- AI + CDK4/6i
  - Ribociclib is the Category 1 Preferred option in combination with an AI for 1L patients
  - Ribociclib is a Category 1 Preferred option in combination with fulvestrant for 1L patients
- Fulvestrant + CDK4/6i
  - Abemaciclib is a Category 1 Preferred option in combination with fulvestrant for 1L patients

In HR+/HER2- eBC, high-risk, node-negative disease is defined as either tumor size >5 cm, or if tumor size 2-5 cm, either grade 2 (with high genomic risk or Ki-67 ≥20%), or grade 3.[1,2]

There is controversy on the choice of CDK4/6i as there are no head-to-head comparisons between the agents, and there are some differences in the study populations in the phase III randomized studies.[2]

NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

Category 1 recommendation:

Based upon high-level evidence, there is uniform consensus that the intervention is appropriate.

Complete the coverage request

Additional clinical data that may support the prescriber's recommendation

- ☐ Adverse events with other treatment options (ie, intolerance)

Close and request a follow-up

- ☐ Provide a list of all attachments
- ☐ Prescribing physician and patient each sign the form(s) or letter(s) if required

IMPORTANT SAFETY INFORMATION (continued)

QT interval prolongation (continued). Avoid KISQALI in patients who are at significant risk of developing torsades de pointes (TdP), including those with:

- congenital long QT syndrome;
- uncontrolled or significant cardiac disease, recent myocardial infarction, heart failure, unstable angina, bradyarrhythmias, uncontrolled hypertension, high degree atrioventricular block, severe aortic stenosis, or uncontrolled hypothyroidism;
- electrolyte abnormalities;
- taking drugs known to prolong QT interval and/or strong CYP3A inhibitors as this may lead to prolongation of the QTcF interval.

Please click here for Important Safety Information, and click here for full Prescribing Information for KISQALI.

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You can work on a PA through CoverMyMeds in parallel with Novartis Oncology Patient Support

Choose the option that works best for you:

1 Start a request

VISIT covermymeds.com

LOG IN to your account

CLICK "New Request" for HCP-initiated requests or "Enter Key" for pharmacy-initiated requests

2 Fill out form

SUBMIT demographic, patient, physician, and medication information for plan review

VERIFY patient eligibility via ePA

3 Answer questions

RESPOND to dynamic clinical questions based on plan criteria

4 Receive results/review

IF APPROVED, a notification will be sent to the HCP and pharmacy

IF DENIED, CoverMyMeds will provide appeal support

1 covermymeds®

- Complete PA requests in minutes and get a response as quickly as in a few hours
- No paper. No fax. No duplicate service
- Electronic patient signatures, if required

Visit CoverMyMeds.com and log in/create an account to get started

>90%

KISQALI PAs are approved[19]

2 Specialty Pharmacies

- KISQALI prescriptions can be filled at an in-network Specialty Pharmacy, a hospital outpatient pharmacy, or an outpatient clinic/practice pharmacy
- Expert pharmacists often coordinate the PA and appeal process, work with the office to gain approval, and can transfer the prescription to the payer-mandated pharmacy if required
- Regardless of preferred Specialty Pharmacy, ALL patients can conveniently self-enroll to receive a dedicated Patient Navigator by visiting www.novartis.com/us-en/patients-and-caregivers/novartis-patient-support-oncology

Click here to view the Specialty Pharmacy Network for KISQALI and call the Specialty Pharmacy of your choice to get started

3 Novartis Patient Support™

Novartis Patient Support provides your practice with comprehensive resources to help your patients start, stay, and save on KISQALI.

Helps to get patients started and guide them along the way with:

- Dedicated assistance with access and reimbursement
- Assistance with relevant savings options for your eligible patients
- Personalized support for your patients on therapy
- Single points of contact for you and your patients

Download the Start Form to get started

ePA, electronic prior authorization; PA, prior authorization.

Please click here for Important Safety Information, and click here for full Prescribing Information for KISQALI.

Sample letters

If a patient is denied coverage and the HCP wishes to appeal the health plan's decision, it is typically required that the HCP explain their clinical rationale for prescribing KISQALI in a Letter of Appeal. This letter addresses each specific reason given for the denial. Review the reason for the denial from the denial letter. Provide clinically relevant and patient-specific information as a guide to address the denial reason in your Letter of Appeal as well as your clinical rationale for prescribing KISQALI.

We have included sample Letters of Appeal and Medical Necessity. The Letter of Medical Necessity may be used to support a PA request or appeal. A plan may require a Letter of Medical Necessity in certain situations, such as when requesting a formulary exception. Each letter should be submitted with a copy of the patient's relevant medical records. Samples of each letter can be downloaded through the links below:

Click here to access sample Letter of Appeal

Click here to access sample Letter of Medical Necessity

IMPORTANT SAFETY INFORMATION (continued)
QT interval prolongation (continued). Based on the observed QT prolongation during treatment, KISQALI may require dose interruption, reduction, or discontinuation.

Please click here for Important Safety Information, and click here for full Prescribing Information for KISQALI.

Important Safety Information for KISQALI

Interstitial lung disease/pneumonitis. Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with KISQALI and other CDK4/6 inhibitors.

In patients with eBC (NATALEE) who received 400 mg KISQALI plus a nonsteroidal aromatase inhibitor (NSAI), 1.5% of patients had ILD/pneumonitis (grade 1/2).

In patients with advanced or mBC (MONALEESA-2, MONALEESA-3, MONALEESA-7), 1.6% of patients had ILD/pneumonitis of any grade, 0.4% had grade 3/4, and 0.1% had a fatal outcome. Additional cases of ILD/pneumonitis have occurred in the postmarketing setting, some resulting in death.

Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis, which may include hypoxia, cough, and dyspnea. In patients who have new or worsening respiratory symptoms suspected to be due to ILD or pneumonitis, interrupt KISQALI immediately and evaluate the patient. Permanently discontinue treatment with KISQALI in patients with severe ILD/pneumonitis or any recurrent symptomatic ILD/pneumonitis.

Severe cutaneous adverse reactions. Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug-induced hypersensitivity syndrome (DiHS)/drug reaction with eosinophilia and systemic symptoms (DRESS) can occur in patients treated with KISQALI.

If signs or symptoms of SCARs occur, interrupt KISQALI until the etiology of the reaction has been determined. Early consultation with a dermatologist is recommended to ensure greater diagnostic accuracy and appropriate management.

If SJS, TEN, or DiHS/DRESS is confirmed, permanently discontinue KISQALI. Do not reintroduce KISQALI in patients who have experienced SCARs or other life-threatening cutaneous reactions during KISQALI treatment.

QT interval prolongation. KISQALI has been shown to prolong the QT interval in a concentration-dependent manner.

Avoid KISQALI in patients who are at significant risk of developing torsades de pointes (TdP), including those with:

- congenital long QT syndrome;
- uncontrolled or significant cardiac disease, recent myocardial infarction, heart failure, unstable angina, bradyarrhythmias, uncontrolled hypertension, high degree atrioventricular block, severe aortic stenosis, or uncontrolled hypothyroidism;
- electrolyte abnormalities;
- taking drugs known to prolong QT interval and/or strong CYP3A inhibitors as this may lead to prolongation of the QTcF interval.

Based on the observed QT prolongation during treatment, KISQALI may require dose interruption, reduction, or discontinuation.

In patients with eBC (NATALEE) who received 400 mg KISQALI plus NSAI, 8 out of 2494 patients (0.3%) had > 500 ms post-baseline QTcF interval value and 50 out of 2494 patients (2%) had > 60 ms QTcF increase from baseline. QTcF prolongation was reversible with dose interruption. The majority of QTcF prolongation occurred within the first 4 weeks of KISQALI. There were no reported cases of torsades de pointes.

In patients with advanced or mBC (MONALEESA-2, MONALEESA-3, and MONALEESA-7) who received 600 mg KISQALI plus NSAI or fulvestrant, 15 of 1054 patients (1.4%) had >500 ms postbaseline QTcF value, and 61 of 1054 (6%) had a >60 ms QTcF increase from baseline. QTcF prolongation was reversible with dose interruption. The majority of QTcF prolongation occurred within the first 4 weeks of KISQALI. There were no reported cases of torsades de pointes. In MONALEESA-2, in the KISQALI + letrozole treatment arm, there was 1 (0.3%) sudden death in a patient with grade 3 hypokalemia and grade 2 QT prolongation. No cases of sudden death were reported in MONALEESA-7 or MONALEESA-3.

Please click here for additional Important Safety Information, and click here for full Prescribing Information for KISQALI.

KISQALI® ribociclib 200 mg tablets

QT interval prolongation (continued). Perform electrocardiogram (ECG) in all patients prior to starting KISQALI. Initiate treatment with KISQALI only in patients with QTcF values <450 ms. Repeat ECG at approximately Day 14 of the first cycle, and as clinically indicated.

Monitor serum electrolytes (including potassium, calcium, phosphorus and magnesium) prior to the initiation of KISQALI, at the beginning of the first 6 cycles, and as clinically indicated. Correct any abnormality before starting KISQALI.

Increased QT prolongation with concomitant use of tamoxifen. KISQALI is not indicated for concomitant use with tamoxifen. Avoid use of tamoxifen with KISQALI. In MONALEESA-7, the observed mean QTcF increase from baseline was >10 ms higher in the tamoxifen + placebo subgroup compared with the nonsteroidal aromatase inhibitor (NSAI) + placebo subgroup. In the placebo arm, an increase of >60 ms from baseline occurred in 6/90 (7%) of patients receiving tamoxifen, and in no patients receiving an NSAI. An increase of >60 ms from baseline in the QTcF interval was observed in 14/87 (16%) of patients in the KISQALI and tamoxifen combination and in 18/245 (7%) of patients receiving KISQALI plus an NSAI.

Hepatotoxicity. In patients with eBC and advanced or mBC, drug-induced liver injury and increases in transaminases occurred with KISQALI.

In patients with eBC (NATALEE) treated with KISQALI, drug-induced liver injury was reported in 9 patients (0.4%), of which 5 were grade ≥3 and 8 had resolved as of the data cutoff. There were 8 (0.3%) clinically confirmed Hy's Law cases (including 4 out of 9 drug-induced liver injury mentioned above), 6 of which had resolved within 303 days and 2 were resolving, all after discontinuation of KISQALI. Grade 3/4 increases in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) occurred in 8% and 4.7%, respectively, and grade 4 increases in ALT (1.5%) and AST (0.8%).

In patients with advanced or mBC (MONALEESA-2, MONALEESA-7, and MONALEESA-3) treated with KISQALI, grade 3 or 4 increases in ALT and AST occurred in 11% and 8%, respectively. Among the patients who had grade ≥3 ALT/AST elevation, the median time to onset was 92 days for the KISQALI plus aromatase inhibitor or fulvestrant treatment arms. The median time to resolution to grade ≤2 was 21 days in the KISQALI plus aromatase inhibitor or fulvestrant treatment arms. In MONALEESA-2 and MONALEESA-3, concurrent elevations in ALT or AST >3x ULN and total bilirubin >2x ULN, with normal alkaline phosphatase, in the absence of cholestasis (Hy's Law) occurred in 6 (1%) patients and all patients recovered after discontinuation of KISQALI.

Perform liver function tests (LFTs) before initiating KISQALI. Monitor LFTs every 2 weeks for the first 2 cycles, at the beginning of each of the subsequent 4 cycles, and as clinically indicated. Based on the severity of the transaminase elevations, KISQALI may require dose interruption, reduction, or discontinuation.

Neutropenia. KISQALI causes concentration-dependent neutropenia. In patients with eBC (NATALEE) who received KISQALI plus NSAI, 94%, including 45% of grade 3/4, had a decrease in neutrophil counts (based on laboratory findings), 63% had an adverse drug reaction of neutropenia, and 0.3% had febrile neutropenia. The median time to grade ≥2 neutropenia was 18 days. The median time to resolution of grade ≥3 neutropenia to grade <3 was 10 days. Treatment discontinuation due to neutropenia was required in 1.1% of patients.

In patients with advanced or metastatic breast cancer (MONALEESA-2, MONALEESA-7, and MONALEESA-3) who received KISQALI plus NSAI or fulvestrant, 75% had neutropenia, 62% had grade 3/4 decrease in neutrophil count (based on laboratory findings), and 1.7% had febrile neutropenia. The median time to grade ≥2 neutropenia was 17 days. The median time to resolution of grade ≥3 neutropenia to grade <3 was 12 days. Treatment discontinuation due to neutropenia was required in 1% of patients.

Perform complete blood count (CBC) before initiating therapy with KISQALI. Monitor CBC every 2 weeks for the first 2 cycles, at the beginning of each of the subsequent 4 cycles, and as clinically indicated. Based on the severity of the neutropenia, KISQALI may require dose interruption, reduction, or discontinuation.

Embryo-fetal toxicity. Based on findings from animal studies and the mechanism of action, KISQALI can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise women of reproductive potential to use effective contraception during therapy with KISQALI and for at least 3 weeks after the last dose.

Adverse reactions in early breast cancer patients. Most common (incidence ≥20%) adverse reactions include infections, nausea, headache, and fatigue.

Laboratory abnormalities. In a clinical trial of patients with early breast cancer, the most common laboratory abnormalities reported in the KISQALI arm (all grades, pooled incidence ≥20%) **were lymphocytes decreased, leukocyte decreased, neutrophil decreased, hemoglobin decreased, alanine aminotransferase increased, aspartate aminotransferase increased, creatinine increased, and platelets decreased.**

Adverse reactions in advanced or metastatic breast cancer patients. Most common (incidence ≥20%) adverse reactions include infections, nausea, fatigue, diarrhea, vomiting, headache, constipation, alopecia, cough, rash, and back pain.

Laboratory abnormalities. Across clinical trials of patients with advanced or metastatic breast cancer, the most common laboratory abnormalities reported in the KISQALI arm (all grades, pooled incidence ≥20%) **were leukocytes decreased, neutrophils decreased, hemoglobin decreased, lymphocytes decreased, AST increased, gamma-glutamyl transferase increased, ALT increased, creatinine increased, platelets decreased, and glucose serum decreased.**

Please click here for full Prescribing Information for KISQALI.

The Bridge Program*

Up to 5 free treatment cycles of KISQALI® (ribociclib) for uninterrupted access while health plan coverage is pursued

Through the Bridge Program,* commercially insured patients waiting for their coverage to take effect for KISQALI and/or FEMARA® (including generic letrozole) may be eligible for an additional supply of KISQALI that could continue for up to 5 treatment cycles.

Once enrolled in Novartis Patient Support™, patients are automatically identified if they are eligible for the Bridge Program* based on the results of the benefits verification.

Privately insured patients waiting for their coverage to take effect for KISQALI and/or FEMARA (including generic letrozole) may be eligible for a supply of KISQALI that could continue for up to 5 treatment cycles.

Once patient's coverage status is determined, Novartis Patient Support will help transition eligible patients to any appropriate financial support offering.

To enroll your eligible patients in this patient support service, submit a completed Novartis Patient Support Start Form or reach out to your Dedicated Novartis ADAR

FDA, US Food and Drug Administration.

***The Bridge Program applies to KISQALI and the KISQALI FEMARA Co-Pack only.** Eligible patients must have private insurance, a valid prescription for KISQALI or the KISQALI FEMARA Co-Pack, and a denial of insurance coverage based on a prior authorization requirement. Program requires the submission of a prior authorization and/or appeal of the coverage denial within the first 90 days of enrollment to remain eligible. Program provides KISQALI for free to eligible patients for up to 5 months, or until they receive insurance coverage approval, whichever occurs earlier. A valid prescription consistent with FDA-approved labeling is required. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program. Patients may be asked to reverify insurance coverage status during the course of the program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Additional limitations may apply. Novartis Pharmaceuticals Corporation reserves the right to rescind, revoke, or amend this Program without notice.

Please click here for Important Safety Information, and click here for full Prescribing Information for KISQALI.

KISQALI® ribociclib 200 mg tablets

Co-Pay Plus

We help make treatment more affordable for your eligible patients through our Co-Pay Plus offer.

$0

Co-Pay Plus Offer*

Patients may be eligible for immediate co-pay savings on their next prescription of KISQALI® (ribociclib), FEMARA® (letrozole) tablets, and/or generic letrozole.

Eligible patients with private insurance may pay $0 per month for KISQALI.*

Have an annual benefit limit per calendar year.

Eligible patients can sign up for the $0 Co-Pay Plus offer:

- Patients can sign up online at https://support.kisqali.com
- Patients can call Novartis Patient Support™ to sign up at 1-866-433-8000
- Providers, with their patients, can complete start form and send to Novartis Patient Support

DoD, US Department of Defense; VA, US Department of Veterans Affairs.

*Co-Pay Plus Terms & Conditions

Offer valid only when used with commercial health insurance. Offer is not available where:

- the patient has federal or state health plan benefits (*e.g.*, Medicare, Medicaid, TRICARE, VA);
- the health plan reimburses for the entire cost of the drug;
- the health plan provides no coverage for the drug; or
- prohibited by law.

The amount of funding available from the Program is subject to an annual limit. Novartis reserves the right to discontinue the availability of co-pay assistance if, at any time, Novartis determines that the patient is subject to a co-pay maximizer program. Co-pay maximizers are programs implemented by health plans in which the amount of the patient's out-of-pocket cost is increased to reflect the availability of support offered by a manufacturer assistance program. The patient is responsible for all costs once available funding from the Program is exhausted.

The Program is designed exclusively for the benefit of the patient. The amount of available funding may be reduced or eliminated if it is not credited by the patient's health plan toward the patient's out-of-pocket obligations (*e.g.*, deductibles, annual out-of-pocket maximums). Program funding may also be reduced or eliminated if the patient's health plan, directly or indirectly, adjusts, reduces, or waives the patient's health plan benefits based on the availability of, or the patient's enrollment in, the Program, or otherwise acts in a manner that materially affects these Terms and Conditions.

Only the patient or their legal guardian or caregiver may enroll the patient in the Program. Health plans, specialty pharmacies, pharmacy benefit managers, and their agents and representatives (individually and collectively "Plan Administrators"), are prohibited from enrolling patients in the Program.

Patients in the Program are responsible for notifying Novartis of any change in their prescription drug health plan coverage that may conflict or otherwise affect compliance with these Terms and Conditions. By accepting Program funding from Novartis on behalf of participating patients, Plan Administrators agree to not take any action that materially affects compliance with these Terms and Conditions.

Patients may not seek reimbursement for the value received from the Program from any other party (*e.g.*, health plans, flexible spending or healthcare savings accounts). Patients are responsible for complying with any applicable limitations and requirements of their health plan related to their use of the Program.

Valid only in the United States and Puerto Rico. For purchasers of FEMARA only, this is NOT valid for Massachusetts patients and is only valid for California patients that meet additional eligibility criteria.

The Program is not health insurance, and may not be combined with any third-party rebate, coupon, or offer. Novartis reserves the right to rescind, revoke, or amend the Program at any time without notice.

Please click here for Important Safety Information, and click here for full Prescribing Information for KISQALI.

Q I have questions about coverage or financial assistance for KISQALI® (ribociclib). Who can I talk to?

A Novartis Patient Support™ is committed to helping patients get the Novartis medicines they need. The Novartis Patient Support team offers resources and support designed specifically to help make the access and reimbursement process easier, including:

- Insurance benefits verification, including information on prior authorizations and denial appeals
- Information about financial assistance that may be available
- Dedicated assistance with access and reimbursement
- Personalized support for your patients on therapy
- Single point of contact for you and your patients

To learn more

Contact your dedicated Novartis Patient Support team at 1-866-433-8000, Monday-Friday, 8:00 AM - 8:00 PM ET, excluding holidays

Q What is the main type of coverage request required for KISQALI® (ribociclib) access?

A PA is the main coverage request for KISQALI.

DESCRIPTION	HOW TO OBTAIN REQUIRED FORMS	PREPARING THE REQUEST	ADDITIONAL CONSIDERATIONS
Requesting coverage for KISQALI may require submission of a PA. PA forms should be completed and submitted to the plan by your office	**Usually located on the health plan's website, through your provider portal, or at CoverMyMeds**	• Provide all requested information • Many specialty pharmacies have the ability to submit a test claim to a payer to confirm coverage of KISQALI • Your Novartis Reimbursement Manager may be able to provide you with PA requirements for specific plans and pharmacy benefit managers (PBMs) • Request a continuation of therapy by providing documentation of patient response to therapy if treatment with KISQALI was previously initiated	**A complete and robust PA can help avoid any future coverage hurdles**

Q What are other types of coverage communications that may be required for KISQALI® (ribociclib)?

A Other types of coverage communications include the Letter of Appeal, Formulary Exception Request, and Letter of Medical Necessity.

COVERAGE REQUEST	DESCRIPTION	HOW TO OBTAIN REQUIRED FORMS	PREPARING THE REQUEST	ADDITIONAL CONSIDERATIONS
Letter of Appeal	Used when a PA request has been denied, and comes from the patient and the physician	Please refer to the plan's specific appeal guidelines, which are often available on their website	• Provide clinically relevant and patient-specific information to address the denial reason found in the denial letter • If this is a second- or third-level appeal, include the letter of denial and medical notes in response to the denial	**If an initial appeal is rejected:** There may be multiple levels of appeal. If the first- and second-level appeals are rejected, additional adjudication may include review by an independent non-insurance-affiliated external review board or hearing

Formulary Exception Request	Used when KISQALI is not listed on a formulary, or if it has a National Drug Code (NDC) block	Usually located on the health plan's website	Include information on prior therapeutic failures and/or why formulary alternatives are not appropriate for this patient
			• Clearly state the rationale for prescribing KISQALI and why the formulary agents are not appropriate. Possible reasons include:
			  ◦ KISQALI efficacy and safety data
			  ◦ Patient had a prior therapeutic failure on formulary agent
			• Plan may require a Letter of Medical Necessity be included with the Formulary Exception Request
				Include information on prior therapeutic failures and/or why formulary alternatives are not appropriate for this patient

Q What are other types of coverage communications that may be required for KISQALI® (ribociclib)? (Continued)

A Other types of coverage communications include the Letter of Appeal, Formulary Exception Request, and Letter of Medical Necessity.

COVERAGE REQUEST	DESCRIPTION	HOW TO OBTAIN REQUIRED FORMS	PREPARING THE REQUEST	ADDITIONAL CONSIDERATIONS
Letter of Medical Necessity	May be required if KISQALI is not on a health plan's formulary; comes from the physician and is signed by the patient	This letter must be written by the physician	• Provide required patient and provider information • Provide complete information, including the patient's stage, menopausal status (if female), and clinical trial results for KISQALI (see pages 3-6 for more information) • **Include specific billing codes where appropriate** **Support your recommendations with the following:** • Patient history, diagnosis with HR+/HER2- BC stage, and current condition and symptoms • Include copies of relevant medical records (payers may want to see if any infections, allergies, or comorbidities are present) **Explain why formulary-preferred agents are not appropriate for Formulary Exception Requests**	• Be sure to include all the listed documents with the letter when you send it to your patient's insurance provider • To close the letter, summarize your recommendation, and provide a phone number should any additional information be required

BC, breast cancer.

Specialty Pharmacy Network for KISQALI

In addition to hospital outpatient pharmacies or outpatient clinic/practice pharmacies, the intended network will include the full-service specialty pharmacies listed below.*

Novartis may modify this network at any time without notice.

PHARMACY	PHONE	FAX	HOURS OF OPERATION
AcariaHealth Specialty Pharmacy	1-800-511-5144	1-877-541-1503	24/7
Accredo Specialty Pharmacy	1-877-732-3431	1-888-302-1028	24/7
Walgreens Specialty Pharmacy	1-800-516-9180	N/A	8 AM to 8 PM ET, Mon to Fri; 8 AM to 5 PM ET, Sat
BioPlus Specialty Pharmacy	1-866-514-8082	1-800-269-5493	24/7
Biologics by McKesson	1-800-850-4306	1-800-823-4506	24/7
CVS Specialty Pharmacy	1-800-237-2767	1-800-323-2445	8 AM to 8 PM ET, Mon to Fri
CenterWell Specialty Pharmacy	1-800-486-2668	1-877-405-7940	8 AM to 11 PM ET, Mon to Fri; 8 AM to 6:30 PM ET, Sat
Onco360 Oncology Pharmacy	1-877-662-6633	1-877-662-6355	24/7
Optum Specialty Pharmacy	1-877-445-6874	1-877-342-4596	24/7

*Novartis does not recommend or require the use of any particular pharmacy. Please refer to the patient's health plan for requirements regarding use of particular specialty pharmacies.

Please click here for Important Safety Information, and click here for full Prescribing Information for KISQALI.

References

1. Kisqali. Prescribing information. Novartis Pharmaceuticals Corp.
2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.1.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed February 3, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org.
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13. Data on file. Novartis Pharmaceuticals Corp; 2020.
14. Im S, Lu Y, Bardia A, et al. Overall survival with ribociclib plus endocrine therapy in breast cancer. *N Engl J Med*. 2019;381(4):307-316.
15. 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 randomized phase 3 trial. *Lancet Oncol*. 2018;19:904-915.
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17. Data on file. CLEE011O12301C (NATALEE). Novartis Pharmaceuticals Corp; 2024.
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19. Data on file. Novartis Pharmaceuticals Corp; 2026.

NOVARTIS

KISQALI® ribociclib 200 mg tablets

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

5/26

FA-11586153

SAMPLE OUTLINE OF LETTER OF APPEAL for KISQALI® (ribociclib)

[Date]
[Health Plan Name]
ATTN: [Department or Medical/Pharmacy Director Name]
[Medical/Pharmacy Director Name]
[Health Plan Address]
[City, State, Zip code]

[Patient's Name]
[Date of Birth]
[Policy ID/Group #]
[Date of Service]

Re: Letter of Appeal for KISQALI® (ribociclib) 200 mg tablets

To Whom It May Concern,

I am writing to request reconsideration of your denial of coverage for KISQALI in combination with [an aromatase inhibitor (AI), fulvestrant], which I have prescribed for the patient referenced above.

I have read and acknowledged your policy for management of drugs for [stage II or III early breast cancer (eBC) with a high risk of recurrence, advanced, metastatic] hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer. I understand you are denying coverage because:

- [reason for the denial]
- [further reasons(s) for the denial, if applicable]

However, I believe the treatment with KISQALI is reasonable, appropriate, and medically necessary for my patient, based on my clinical experience, the patient's condition, and their medical history.

[If KISQALI is being prescribed for eBC]: KISQALI is indicated in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor HR positive, HER2 negative stage II and III early breast cancer at high risk of recurrence.

[If KISQALI is being prescribed in combination with an AI]: KISQALI is indicated for the treatment of adult patients with hormone receptor HR+/HER2- advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy.

[If KISQALI is being prescribed in combination with fulvestrant]: KISQALI is indicated for the treatment of adult patients with hormone receptor HR+/HER2- advanced or metastatic breast cancer in combination with fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men.

Clinical Information to Support Appeal

[Patient's name] is [a/an] [age]-year-old [male or (menopausal status) female] who has been diagnosed with HR+/HER2- [early stage, advanced, metastatic] breast cancer as of [date]. This patient has been in my care since [date]. [Include supporting information as requested by the plan in their denial letter and any clinical attributes of KISQALI that are relevant to the patient.]

[Additional information that may be supportive of the appeal should be included if not previously provided in the initial request, where applicable:

- Clinical trial data found in the KISQALI Prescribing Information
- If applicable, rationale for why the health plan's preferred therapies are not appropriate for your patient]

National Comprehensive Cancer Network® (NCCN®)

- [NCCN recognizes ribociclib (KISQALI®) as a Category 1 Preferred CDK4/6 inhibitor in combination with an AI for appropriate patients with HR+/HER2- eBC—the only one to receive this designation for both high-risk node-negative and any node-positive disease

  KISQALI is approved for use in combination with an AI; node-positive disease excludes patients with microscopic nodal involvement.[1,2]

  High-risk node-negative disease is defined as either tumor size >5 cm, or if tumor size 2-5 cm, either grade 2 (with high genomic risk or Ki-67 ≥20%) or grade 3.[1,2]

  NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.[1]]

  OR

- [NCCN differentiates ribociclib (KISQALI®) as the only Category 1 Preferred first-line treatment option in combination with an AI for appropriate patients with HR+/HER2- metastatic breast cancer

  There is controversy on the choice of CDK4/6i as there are no head-to-head comparisons between the agents and there are some differences in the study populations in the phase III randomized studies.

  NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.[1]]

Summary

Based on my professional experience, KISQALI is appropriate, medically necessary, and supported by the patient's individual medical history. A copy of the denial letter is included along with medical notes in response to the denial. If you have any further questions about this matter, please contact me at [physician's phone number] or via email at [physician's email].

Thank you for your time and consideration.

Sincerely,
[Physician's Signature]
[Physician's Name]
[NPI Number]

Enclosures

[List and attach additional documents, which may include a denial letter, Letter of Medical Necessity, copies of original request, prescribing information, clinical notes/medical records, laboratory work including documentation of HR+/HER2- status, and imaging results.]

Indications

KISQALI is indicated:

- in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer (eBC) at high risk of recurrence
- for the treatment of adults with HR-positive, HER2-negative advanced or metastatic breast cancer (mBC) in combination with:
  - an aromatase inhibitor as initial endocrine-based therapy; or
  - fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy

IMPORTANT SAFETY INFORMATION

Interstitial lung disease/pneumonitis. Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with KISQALI and other CDK4/6 inhibitors.

In patients with eBC (NATALEE) who received 400 mg KISQALI plus a nonsteroidal aromatase inhibitor (NSAI), 1.5% of patients had ILD/pneumonitis (grade 1/2).

In patients with advanced or mBC (MONALEESA-2, MONALEESA-3, MONALEESA-7), 1.6% of patients had ILD/pneumonitis of any grade, 0.4% had grade 3/4, and 0.1% had a fatal outcome. Additional cases of ILD/pneumonitis have occurred in the postmarketing setting, some resulting in death.

Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis, which may include hypoxia, cough, and dyspnea. In patients who have new or worsening respiratory symptoms suspected to be due to ILD or pneumonitis, interrupt KISQALI immediately and evaluate the patient. Permanently discontinue treatment with KISQALI in patients with severe ILD/pneumonitis or any recurrent symptomatic ILD/pneumonitis.

Severe cutaneous adverse reactions. Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug-induced hypersensitivity syndrome (DiHS)/drug reaction with eosinophilia and systemic symptoms (DRESS) can occur in patients treated with KISQALI.

If signs or symptoms of SCARs occur, interrupt KISQALI until the etiology of the reaction has been determined. Early consultation with a dermatologist is recommended to ensure greater diagnostic accuracy and appropriate management.

If SJS, TEN, or DiHS/DRESS is confirmed, permanently discontinue KISQALI. Do not reintroduce KISQALI in patients who have experienced SCARs or other life-threatening cutaneous reactions during KISQALI treatment.

QT interval prolongation. KISQALI has been shown to prolong the QT interval in a concentration-dependent manner.

Avoid KISQALI in patients who are at significant risk of developing torsades de pointes (TdP), including those with:

- congenital long QT syndrome;
- uncontrolled or significant cardiac disease, recent myocardial infarction, heart failure, unstable angina, bradyarrhythmias, uncontrolled hypertension, high degree atrioventricular block, severe aortic stenosis, or uncontrolled hypothyroidism;
- electrolyte abnormalities;
- taking drugs known to prolong QT interval and/or strong CYP3A inhibitors as this may lead to prolongation of the QTcF interval.

Based on the observed QT prolongation during treatment, KISQALI may require dose interruption, reduction, or discontinuation.

In patients with eBC (NATALEE) who received 400 mg KISQALI plus NSAI, 8 out of 2494 patients (0.3%) had

> 500 ms post-baseline QTcF interval value and 50 out of 2494 patients (2%) had > 60 ms QTcF increase from baseline. QTcF prolongation was reversible with dose interruption. The majority of QTcF prolongation occurred within the first 4 weeks of KISQALI. There were no reported cases of torsades de pointes.

In patients with advanced or mBC (MONALEESA-2, MONALEESA-3, and MONALEESA-7) who received 600 mg KISQALI plus NSAI or fulvestrant, 15 of 1054 patients (1.4%) had >500 ms postbaseline QTcF value, and 61 of 1054 (6%) had a >60 ms QTcF increase from baseline. QTcF prolongation was reversible with dose interruption. The majority of QTcF prolongation occurred within the first 4 weeks of KISQALI. There were no reported cases of torsades de pointes. In MONALEESA-2, in the KISQALI + letrozole treatment arm, there was 1 (0.3%) sudden death in a patient with grade 3 hypokalemia and grade 2 QT prolongation. No cases of sudden death were reported in MONALEESA-7 or MONALEESA-3.

Perform electrocardiogram (ECG) in all patients prior to starting KISQALI. Initiate treatment with KISQALI only in patients with QTcF values <450 ms. Repeat ECG at approximately Day 14 of the first cycle, and as clinically indicated.

Monitor serum electrolytes (including potassium, calcium, phosphorus and magnesium) prior to the initiation of KISQALI, at the beginning of the first 6 cycles, and as clinically indicated. Correct any abnormality before starting KISQALI.

Increased QT prolongation with concomitant use of tamoxifen. KISQALI is not indicated for concomitant use with tamoxifen. Avoid use of tamoxifen with KISQALI. In MONALEESA-7, the observed mean QTcF increase from baseline was >10 ms higher in the tamoxifen + placebo subgroup compared with the nonsteroidal aromatase inhibitor (NSAI) + placebo subgroup. In the placebo arm, an increase of >60 ms from baseline occurred in 6/90 (7%) of patients receiving tamoxifen, and in no patients receiving an NSAI. An increase of

>60 ms from baseline in the QTcF interval was observed in 14/87 (16%) of patients in the KISQALI and tamoxifen combination and in 18/245 (7%) of patients receiving KISQALI plus an NSAI.

Hepatotoxicity. In patients with eBC and advanced or mBC, drug-induced liver injury and increases in transaminases occurred with KISQALI.

In patients with eBC (NATALEE) treated with KISQALI, drug-induced liver injury was reported in 9 patients (0.4%), of which 5 were grade ≥3 and 8 had resolved as of the data cutoff. There were 8 (0.3%) clinically confirmed Hy's Law cases (including 4 out of 9 drug-induced liver injury mentioned above), 6 of which had resolved within 303 days and 2 were resolving, all after discontinuation of KISQALI. Grade 3/4 increases in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) occurred in 8% and 4.7%, respectively, and grade 4 increases in ALT (1.5%) and AST (0.8%).

In patients with advanced or mBC (MONALEESA-2, MONALEESA-7, and MONALEESA-3) treated with KISQALI, grade 3 or 4 increases in ALT and AST occurred in 11% and 8%, respectively. Among the patients who had grade ≥3 ALT/AST elevation, the median time to onset

was 92 days for the KISQALI plus aromatase inhibitor or fulvestrant treatment arms. The median time to resolution to grade ≤2 was 21 days in the KISQALI plus aromatase inhibitor or fulvestrant treatment arms. In MONALEESA-2 and MONALEESA-3, concurrent elevations in ALT or AST >3x ULN and total bilirubin >2x ULN, with normal alkaline phosphatase, in the absence of cholestasis (Hy's Law) occurred in 6 (1%) patients and all patients recovered after discontinuation of KISQALI.

Perform liver function tests (LFTs) before initiating KISQALI. Monitor LFTs every 2 weeks for the first 2 cycles, at the beginning of each of the subsequent 4 cycles, and as clinically indicated. Based on the severity of the transaminase elevations, KISQALI may require dose interruption, reduction, or discontinuation.

Neutropenia. KISQALI causes concentration-dependent neutropenia. In patients with eBC (NATALEE) who received KISQALI plus NSAI, 94%, including 45% of grade 3/4, had a decrease in neutrophil counts (based on laboratory findings), 63% had an adverse drug reaction of neutropenia, and 0.3% had febrile neutropenia. The median time to grade ≥2 neutropenia was 18 days. The median time to resolution of grade ≥3 neutropenia to grade <3 was 10 days. Treatment discontinuation due to neutropenia was required in 1.1% of patients.

In patients with advanced or metastatic breast cancer (MONALEESA-2, MONALEESA-7, and MONALEESA-3) who received KISQALI plus NSAI or fulvestrant, 75% had neutropenia, 62% had grade 3/4 decrease in neutrophil count (based on laboratory findings), and 1.7% had febrile neutropenia. The median time to grade ≥2 neutropenia was 17 days. The median time to resolution of grade ≥3 neutropenia to grade <3 was 12 days.

Treatment discontinuation due to neutropenia was required in 1% of patients.

Perform complete blood count (CBC) before initiating therapy with KISQALI. Monitor CBC every 2 weeks for the first 2 cycles, at the beginning of each of the subsequent 4 cycles, and as clinically indicated. Based on the severity of the neutropenia, KISQALI may require dose interruption, reduction, or discontinuation.

Embryo-fetal toxicity. Based on findings from animal studies and the mechanism of action, KISQALI can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise women of reproductive potential to use effective contraception during therapy with KISQALI and for at least 3 weeks after the last dose.

Adverse reactions in early breast cancer patients. Most common (incidence ≥20%) adverse reactions include infections, nausea, headache, and fatigue.

Laboratory abnormalities. In a clinical trial of patients with early breast cancer, the most common laboratory abnormalities reported in the KISQALI arm (all grades, pooled incidence ≥20%) **were lymphocytes decreased, leukocyte decreased, neutrophil decreased, hemoglobin decreased, alanine aminotransferase increased, aspartate aminotransferase increased, creatinine increased, and platelets decreased.**

Adverse reactions in advanced or metastatic breast cancer patients. Most common (incidence ≥20%) adverse reactions include infections, nausea, fatigue, diarrhea, vomiting, headache, constipation, alopecia, cough, rash, and back pain.

Laboratory abnormalities. Across clinical trials of patients with advanced or metastatic breast cancer, the most common laboratory abnormalities reported in the KISQALI arm (all grades, pooled incidence ≥20%) **were leukocytes decreased, neutrophils decreased, hemoglobin decreased, lymphocytes decreased, AST increased, gamma-glutamyl transferase increased, ALT increased, creatinine increased, platelets decreased, and glucose serum decreased.**

Please click here to see full Prescribing Information.

References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.1.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed February 3, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org. **2.** Kisqali. Prescribing information. Novartis Pharmaceuticals Corp.

SAMPLE OUTLINE OF LETTER OF MEDICAL NECESSITY FOR KISQALI® (ribociclib)

[Date]
[Health Plan Name]
ATTN: [Department or Medical/Pharmacy Director Name]
[Medical/Pharmacy Director Name]
[Health Plan Address]
[City, State, Zip code]

[Patient's Name]
[Date of Birth]
[Policy ID/Group #]
[Date of Service]

Re: Letter of Medical Necessity for KISQALI® (ribociclib) 200 mg tablets

To Whom It May Concern,

I am writing this letter on behalf of [patient's name] to request coverage for KISQALI for the treatment of [Stage II or III early breast cancer (eBC) with a high risk of recurrence, advanced, metastatic] hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer in combination with [an aromatase inhibitor (AI), fulvestrant]. This letter provides the clinical rationale and relevant information about the patient's medical history and treatment.

[If KISQALI is being prescribed for early breast cancer]: KISQALI is indicated in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor HR positive, HER2 negative stage II and III early breast cancer at high risk of recurrence.

[If KISQALI is being prescribed in combination with an aromatase inhibitor]: KISQALI is indicated for the treatment of adult patients with hormone receptor HR+/HER2- advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy.

[If KISQALI is being prescribed in combination with fulvestrant]: KISQALI is indicated for the treatment of adult patients with hormone receptor HR+/HER2- advanced or metastatic breast cancer in combination with fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men.

Patient's Diagnosis and Medical History

[Please include overview of disease course of the patient, including diagnosis of HR+/HER2- breast cancer, history and stage of disease, prior treatments, surgeries, and other relevant medical history.]

Clinical Rationale

[Provide clinical rationale for why your patient will benefit from KISQALI. This may include:

- Clinical trial data found in the KISQALI Prescribing Information
- If applicable, rationale for why the health plan's preferred therapies are not appropriate for your patient

If your patient is already taking KISQALI, describe their response to KISQALI and explain why it is not in the best interest of your patient to switch therapies.]

HR+/HER2- Stage II and III Early Breast Cancer

[In my medical opinion, the most appropriate treatment for my patient is KISQALI in combination with an AI, based on efficacy and safety data.]

HR+/HER2- Advanced or Metastatic Breast Cancer

[In my medical opinion, the most appropriate treatment for my patient is KISQALI in combination with [fulvestrant or an AI], based on efficacy and safety data.]

National Comprehensive Cancer Network® (NCCN®)

- [NCCN recognizes ribociclib (KISQALI®) as a Category 1 Preferred CDK4/6 inhibitor in combination with an AI for appropriate patients with HR+/HER2- eBC—the only one to receive this designation for both high-risk node-negative and any node-positive disease

  KISQALI is approved for use in combination with an AI; node-positive disease excludes patients with microscopic nodal involvement.[1,2]

  High-risk node-negative disease is defined as either tumor size >5 cm, or if tumor size 2-5 cm, either grade 2 (with high genomic risk or Ki-67 ≥20%) or grade 3.[1,2]

  NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.[1]]

  OR

- [NCCN differentiates ribociclib (KISQALI®) as the only Category 1 Preferred first-line treatment option in combination with an AI for appropriate patients with HR+/HER2- metastatic breast cancer

  There is controversy on the choice of CDK4/6i as there are no head-to-head comparisons between the agents and there are some differences in the study populations in the phase III randomized studies.

  NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.[1]]

Based on my professional experience, KISQALI is appropriate, medically necessary, and supported by the patient's individual medical history. Attached are relevant medical records to support my rationale. If you have any further questions about this matter, please contact me at [physician's phone number] or via email at [physician's email].

Thank you for your time and consideration.

Sincerely,
[Physician's Signature]
[Physician's Name]
[NPI Number]

Enclosures

[List and attach additional medical records, which may include clinical notes, laboratory work including documentation of HR+/HER2- status, imaging results, and prescribing information.]

Indications

KISQALI is indicated:

- in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer (eBC) at high risk of recurrence
- for the treatment of adults with HR-positive, HER2-negative advanced or metastatic breast cancer (mBC) in combination with:
  - an aromatase inhibitor as initial endocrine-based therapy; or
  - fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy

IMPORTANT SAFETY INFORMATION

Interstitial lung disease/pneumonitis. Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with KISQALI and other CDK4/6 inhibitors.

In patients with eBC (NATALEE) who received 400 mg KISQALI plus a nonsteroidal aromatase inhibitor (NSAI), 1.5% of patients had ILD/pneumonitis (grade 1/2).

In patients with advanced or mBC (MONALEESA-2, MONALEESA-3, MONALEESA-7), 1.6% of patients had ILD/pneumonitis of any grade, 0.4% had grade 3/4, and 0.1% had a fatal outcome. Additional cases of ILD/pneumonitis have occurred in the postmarketing setting, some resulting in death.

Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis, which may include hypoxia, cough, and dyspnea. In patients who have new or worsening respiratory symptoms suspected to be due to ILD or pneumonitis, interrupt KISQALI immediately and evaluate the patient. Permanently discontinue treatment with KISQALI in patients with severe ILD/pneumonitis or any recurrent symptomatic ILD/pneumonitis.

Severe cutaneous adverse reactions. Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug-induced hypersensitivity syndrome (DiHS)/drug reaction with eosinophilia and systemic symptoms (DRESS) can occur in patients treated with KISQALI.

If signs or symptoms of SCARs occur, interrupt KISQALI until the etiology of the reaction has been determined. Early consultation with a dermatologist is recommended to ensure greater diagnostic accuracy and appropriate management.

If SJS, TEN, or DiHS/DRESS is confirmed, permanently discontinue KISQALI. Do not reintroduce KISQALI in patients who have experienced SCARs or other life-threatening cutaneous reactions during KISQALI treatment.

QT interval prolongation. KISQALI has been shown to prolong the QT interval in a concentration-dependent manner.

Avoid KISQALI in patients who are at significant risk of developing torsades de pointes (TdP), including those with:

- congenital long QT syndrome;
- uncontrolled or significant cardiac disease, recent myocardial infarction, heart failure, unstable angina, bradyarrhythmias, uncontrolled hypertension, high degree atrioventricular block, severe aortic stenosis, or uncontrolled hypothyroidism;
- electrolyte abnormalities;
- taking drugs known to prolong QT interval and/or strong CYP3A inhibitors as this may lead to prolongation of the QTcF interval.

Based on the observed QT prolongation during treatment, KISQALI may require dose interruption, reduction, or discontinuation.

In patients with eBC (NATALEE) who received 400 mg KISQALI plus NSAI, 8 out of 2494 patients (0.3%) had > 500 ms post-baseline QTcF interval value and 50 out of 2494 patients (2%) had > 60 ms QTcF increase from baseline. QTcF prolongation was reversible with dose interruption. The majority of QTcF prolongation occurred within the first 4 weeks of KISQALI. There were no reported cases of torsades de pointes.

In patients with advanced or mBC (MONALEESA-2, MONALEESA-3, and MONALEESA-7) who received 600 mg KISQALI plus NSAI or fulvestrant, 15 of 1054 patients (1.4%) had >500 ms postbaseline QTcF value, and 61 of 1054 (6%) had a >60 ms QTcF increase from baseline. QTcF prolongation was reversible with dose interruption. The majority of QTcF prolongation occurred within the first 4 weeks of KISQALI. There were no reported cases of torsades de pointes. In MONALEESA-2, in the KISQALI + letrozole treatment arm, there was 1 (0.3%) sudden death in a patient with grade 3 hypokalemia and grade 2 QT prolongation. No cases of sudden death were reported in MONALEESA-7 or MONALEESA-3.

Perform electrocardiogram (ECG) in all patients prior to starting KISQALI. Initiate treatment with KISQALI only in patients with QTcF values <450 ms. Repeat ECG at approximately Day 14 of the first cycle, and as clinically indicated.

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Perform liver function tests (LFTs) before initiating KISQALI. Monitor LFTs every 2 weeks for the first 2 cycles, at the beginning of each of the subsequent 4 cycles, and as clinically indicated. Based on the severity of the transaminase elevations, KISQALI may require dose interruption, reduction, or discontinuation.

Neutropenia. KISQALI causes concentration-dependent neutropenia. In patients with eBC (NATALEE) who received KISQALI plus NSAI, 94%, including 45% of grade 3/4, had a decrease in neutrophil counts (based on laboratory findings), 63% had an adverse drug reaction of neutropenia, and 0.3% had febrile neutropenia. The median time to grade ≥2 neutropenia was 18 days. The median time to resolution of grade ≥3 neutropenia to grade <3 was 10 days. Treatment discontinuation due to neutropenia was required in 1.1% of patients.

In patients with advanced or metastatic breast cancer (MONALEESA-2, MONALEESA-7, and MONALEESA-3) who received KISQALI plus NSAI or fulvestrant, 75% had neutropenia, 62% had grade 3/4 decrease in neutrophil count (based on laboratory findings), and 1.7% had febrile neutropenia. The median time to grade ≥2 neutropenia was 17 days. The median time to resolution of grade ≥3 neutropenia to grade <3 was 12 days. Treatment discontinuation due to neutropenia was required in 1% of patients.

Perform complete blood count (CBC) before initiating therapy with KISQALI. Monitor CBC every 2 weeks for the first 2 cycles, at the beginning of each of the subsequent 4 cycles, and as clinically indicated. Based on the severity of the neutropenia, KISQALI may require dose interruption, reduction, or discontinuation.

Embryo-fetal toxicity. Based on findings from animal studies and the mechanism of action, KISQALI can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise women of reproductive potential to use effective contraception during therapy with KISQALI and for at least 3 weeks after the last dose.

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Laboratory abnormalities. In a clinical trial of patients with early breast cancer, the most common laboratory abnormalities reported in the KISQALI arm (all grades, pooled incidence ≥20%) **were lymphocytes decreased, leukocyte decreased, neutrophil decreased, hemoglobin decreased, alanine aminotransferase increased, aspartate aminotransferase increased, creatinine increased, and platelets decreased.**

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Please click here to see full Prescribing Information for KISQALI.