KISQALI Access Support Guide

CLINICAL CONSIDERATIONS

Understand clinical trial results
to communicate the appropriate
indication for KISQALI and
KISQALI FEMARA Co-Pack
and the treatment goal
for each patient to health plans

Review the
Clinical Considerations for KISQALI

COVERAGE REQUEST SELF-CHECK

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

FINANCIAL RESOURCES

Financial support is available
for KISQALI patients with
the FREE treatment voucher and
KISQALI FEMARA Co-Pack
$0 co-pay offer

Download the
FREE treatment voucher here,
and the $0 co-pay 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 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.

NOVARTIS

Femara® (letrozole) 2.5 mg tablets

KISQALI® ribociclib 200 mg tablets

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

It is important to identify the appropriate indication and treatment goal(s) for male and female patients.

KISQALI in combination with an aromatase inhibitor[1]:

- KISQALI is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy

KISQALI in combination with fulvestrant[1]:

- KISQALI is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative 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

KISQALI FEMARA Co-Pack[2]:

- The KISQALI FEMARA Co-Pack is indicated as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer

NCCN CATEGORY 1 UPDATE

NCCN now differentiates ribociclib (KISQALI®) as the only Category 1 Preferred 1L treatment option in combination with an AI for patients with HR+/HER2- mBC[3]

MONALEESA-2, statistically significant overall survival in 1L postmenopausal patients: At a median follow-up of 80 months, 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. PFS was the primary end point.

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; AI=aromatase inhibitor; ET=endocrine therapy; HER2-=human epidermal growth factor receptor 2-negative; HR=hazard ratio; HR+=hormone receptor-positive; mBC=metastatic breast cancer; mPFS=median progression-free survival; NR=not reached; OS=overall survival; TTD=time to deterioration.

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.

Across clinical trials in patients with advanced or metastatic breast cancer treated with KISQALI in combination with an aromatase inhibitor or fulvestrant ("KISQALI treatment groups"), 1.2% of patients treated with KISQALI had ILD/pneumonitis of any grade, 0.3% had grade 3/4, and 0.1% had a fatal outcome. Additional cases of ILD/pneumonitis have been observed in the postmarketing setting, with fatalities reported.

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Select clinical trial results for KISQALI

MONALEESA-2: KISQALI + letrozole, postmenopausal | **MONALEESA-7: KISQALI + NSAI + goserelin, premenopausal** | **MONALEESA-3: KISQALI + fulvestrant, postmenopausal**

MONALEESA-2: Postmenopausal women, in combination with letrozole, as a first-line therapy[1,4-7]

Clinical study description	In the MONALEESA-2 clinical trial, postmenopausal women with HR+/HER2- advanced breast cancer and no prior endocrine therapy for advanced disease received KISQALI in combination with letrozole.
Progression-free survival (primary end point)	For patients receiving KISQALI + letrozole, at a median follow-up of 15 months, median progression-free survival 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*<0.0001. In an updated analysis with a median follow-up of 26 months, mPFS was 25.3 months (95% CI: 23.0-30.3) vs 16.0 months (95% CI: 13.4-18.2).
Overall survival	For patients receiving KISQALI + letrozole, at a median follow-up of 80 months, the median overall survival 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 a hazard ratio of 0.765 (95% CI: 0.628-0.932); *P*=0.004.
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.

OVERALL SURVIVAL BENEFIT WITH KISQALI INCREASED OVER TIME[7] At 6 years, the survival rate of patients receiving KISQALI + letrozole was 44% vs 32% with placebo + letrozole

KISQALI—a proven overall survival advantage for first-line postmenopausal patients in combination with an AI[1]

AI=aromatase inhibitor; ARs=adverse reactions; HER2-=human epidermal growth factor receptor 2-negative; HR=hazard ratio; HR+=hormone receptor-positive; NR=not reached; NSAI=nonsteroidal aromatase inhibitor.

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 treatment with KISQALI immediately and evaluate the patient. Permanently discontinue treatment with KISQALI in patients with recurrent symptomatic or severe ILD/pneumonitis.

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

KISQALI® ribociclib 200 mg tablets

Select clinical trial results for KISQALI

MONALEESA-2:
KISQALI + letrozole, postmenopausal

MONALEESA-7:
KISQALI + NSAI + goserelin, premenopausal

MONALEESA-3:
KISQALI + fulvestrant, postmenopausal

MONALEESA-7: Premenopausal women, in combination with an NSAI and goserelin, as a first-line therapy[1,8-10]

Clinical study description	In the MONALEESA-7 clinical trial for KISQALI, pre/perimenopausal women with HR+/HER2- metastatic breast cancer received KISQALI in combination with an NSAI and goserelin as a first-line therapy for advanced disease.
Progression-free survival (primary end point)	At a median follow-up of 19 months, KISQALI achieved 27.5 months median progression-free survival (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]).
Overall survival	KISQALI significantly improved overall survival for pre/perimenopausal women in the MONALEESA-7 clinical trial. At a median follow-up of 54 months (exploratory analysis*), median overall survival was 58.7 months with KISQALI + NSAI + goserelin (95% CI: 48.5-NR) vs 47.7 months with NSAI + goserelin (95% CI: 41.2-55.4); HR=0.798 (95% CI: 0.615-1.035)
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, gammaglutamyl transferase increased, aspartate aminotransferase increased, infections, arthralgia, alanine aminotransferase increased, nausea, platelets decreased, and alopecia.

Only KISQALI—a proven overall survival advantage in a trial dedicated to first-line premenopausal patients

AI=aromatase inhibitor; ARs=adverse reactions; HER2-=human epidermal growth factor receptor 2-negative; HR=hazard ratio; HR+=hormone receptor-positive; NR=not reached; NSAI=nonsteroidal aromatase inhibitor.
*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.

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KISQALI® ribociclib 200 mg tablets

Select clinical trial results for KISQALI

MONALEESA-2: KISQALI + letrozole, postmenopausal | **MONALEESA-7: KISQALI + NSAI + goserelin, premenopausal** | **MONALEESA-3: KISQALI + fulvestrant, postmenopausal**

MONALEESA-3: Postmenopausal women, in combination with fulvestrant, as a first-line therapy for advanced disease or a second-line therapy after progression on endocrine therapy[1,11,12]

Clinical study description	In the MONALEESA-3 clinical trial for KISQALI, postmenopausal women with HR+/HER2- metastatic breast cancer received KISQALI in combination with fulvestrant as a first-line therapy for advanced disease, or a second-line therapy after progression on endocrine therapy.
Progression-free survival (primary end point)	In the primary analysis at a median follow-up of 20 months, KISQALI significantly improved progression-free survival in the clinical study, with 20.5 months median progression-free survival (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*<0.0001).
Overall survival	For patients receiving KISQALI, at a median follow-up of 39 months, median overall survival with KISQALI + fulvestrant was not reached (95% CI: 42.5-NR) vs 40.0 months with placebo + fulvestrant (95% CI: 37.0-NR); *P*=0.00455 (HR=0.724 [95% CI: 0.568-0.924]). At a median follow-up of 71 months (exploratory analysis*), median overall survival was 67.6 months with KISQALI + fulvestrant (95% CI: 59.6-NR) vs 51.8 months with fulvestrant (95% CI: 40.4-61.2); HR=0.673 (95% CI: 0.504-0.899).
Safety profile	The most common (≥20% on the KISQALI arm and ≥2% higher than placebo) adverse reactions, 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.

Only KISQALI—a proven overall survival advantage in a trial dedicated to first- and second-line postmenopausal patients in combination with fulvestrant

HER2-=human epidermal growth factor receptor 2-negative; HR=hazard ratio; HR+=hormone receptor-positive; NR=not reached.
*Results should be interpreted with caution as there was no control for type-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. Consultation with a dermatologist is recommended.

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

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

Each health plan manages access to KISQALI differently. Checklists and sample letters on the following pages can help ensure you are providing 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 advanced 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:

- ☐ Advanced 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

- ☐ Menopausal status (if female)
- ☐ Documentation that the patient's breast cancer is HR+/HER2-
- ☐ Relevant medical records 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 advanced breast cancer symptoms at the time of KISQALI prescription and any changes in symptoms since treatment began
- ☐ Indicate whether the patient has been treated with previous therapy for advanced breast cancer

HER2-=human epidermal growth factor receptor 2-negative; HR+=hormone receptor-positive.

IMPORTANT SAFETY INFORMATION (continued)
QT interval prolongation. KISQALI® (ribociclib) and the KISQALI® (ribociclib) FEMARA® (letrozole) Co-Pack have been shown to prolong the QT interval in a concentration-dependent manner. Based on the observed QT prolongation during treatment, KISQALI may require dose interruption, reduction, or discontinuation. In MONALEESA-2 and MONALEESA-7, in patients with advanced or metastatic breast cancer who received the combination of KISQALI plus an aromatase inhibitor, 7 of 574 patients (1%) had >500 ms postbaseline QTcF value, and 29 of 574 patients (5%) had a >60 ms increase from baseline in QTcF intervals.

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Communicate the benefits of KISQALI

Overall survival data, along with 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. In some cases, KISQALI may be the only CDK4/6 inhibitor FDA-approved for the prescribed use.

KISQALI is the only CDK4/6i with statistically significant OS across all three phase III trials

Provide clinical data in support of the prescriber's recommendation

KISQALI—the only CDK4/6 inhibitor to achieve statistically significant overall survival in a broad range of patients across 3 phase III trials[1,5-10,12,14,15]

☐ In postmenopausal women, in combination with letrozole, as a first-line therapy:
- Over 5 years mOS[1]

Click here for MONALEESA-2 data

☐ In premenopausal women, in combination with an NSAI and goserelin, as a first-line therapy[1]:
- Nearly 5 years mOS[8]

Click here for MONALEESA-7 data

☐ In postmenopausal women, in combination with fulvestrant, as a first-line therapy for advanced disease or as a second-line therapy after progression on endocrine therapy[1]:
- Over 5.5 years mOS[12]

Click here for MONALEESA-3 data

For more information on these trials, please see the following publications:

- Hortobagyi GN, et al. *Ann Oncol*. 2018;29(7):1541-1547. **Click here** to access the full publication.
- Hortobagyi GN, et al. *N Engl J Med*. 2016;375(18):1738-1748. **Click here** to access the full publication.
- Hortobagyi GN, et al. *N Engl J Med*. 2022;386(10):942-950. **Click here** to access the full publication.
- Im S, et al. *N Engl J Med*. 2019;381(4):307-316. **Click here** to access the full publication.
- Tripathy D, et al. *Lancet Oncol*. 2018;19:904-915. **Click here** to access the publication summary.
- Slamon DJ, et al. *Ann Oncol*. 2021;32(8):1015-1024. **Click here** to access the full publication.
- Slamon DJ, et al. *N Engl J Med*. 2020;382(6):514-524. **Click here** to access the full publication.

AI=aromatase inhibitor; CDK=cyclin-dependent kinase; FDA=US Food and Drug Administration; HER2-=human epidermal growth factor receptor 2-negative; HR+=hormone receptor-positive; mOS=median overall survival; NSAI=nonsteroidal aromatase inhibitor.
*Results should be interpreted with caution as there was no control for type-error.

Clinical trial results may be useful in communicating the clinical benefits of KISQALI to health plans.
Reminder: KISQALI is not indicated for concomitant use with tamoxifen

IMPORTANT SAFETY INFORMATION (continued)
QT interval prolongation (continued). These electrocardiogram (ECG) changes were reversible with dose interruption and most occurred within the first 4 weeks of treatment. No cases of torsades de pointes were reported. In MONALEESA-2, on 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.

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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

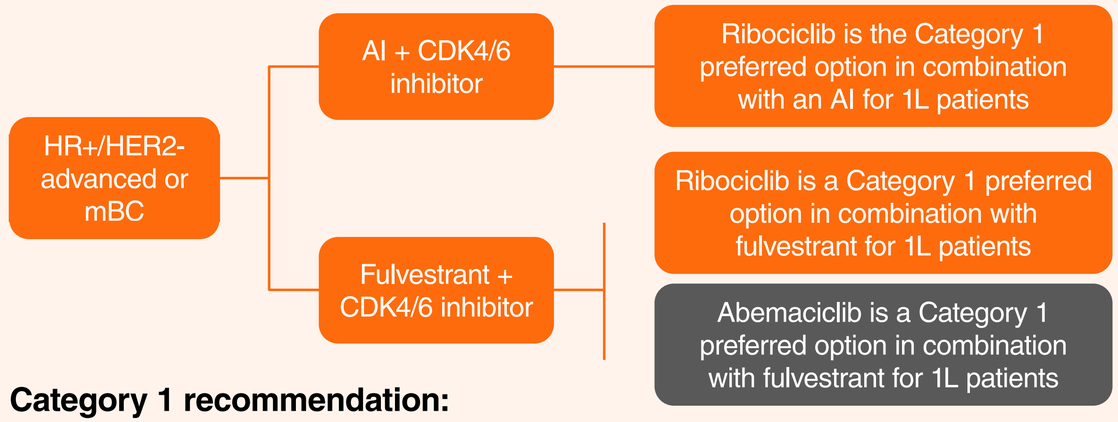
NCCN now differentiates ribociclib (KISQALI®) as the only Category 1 Preferred 1L treatment option in combination with an AI for patients with HR+/HER2- mBC[3]

MONALEESA-2, statistically significant overall survival in 1L postmenopausal patients: At a median follow-up of 80 months, 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. PFS was the primary end point.

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.

Postmenopausal or Premenopausal Patients Receiving Ovarian Ablation or Suppression[3]



Category 1 recommendation:

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

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.

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

- ☐ Consider asking the health plan to also send a copy of the coverage determination to the patient
- ☐ Provide a list of all attachments
- ☐ Prescribing physician and patient each sign the form(s) or letter(s) if required

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IMPORTANT SAFETY INFORMATION (continued)
QT interval prolongation (continued). Assess ECG prior to initiation of treatment. Initiate treatment with KISQALI or the KISQALI FEMARA Co-Pack only in patients with QTcF values <450 ms. Repeat ECG at approximately Day 14 of the first cycle, at the beginning of the second cycle, and as clinically indicated. Monitor serum electrolytes (including potassium, calcium, phosphorus, and magnesium) prior to the initiation of treatment, at the beginning of each of the first 6 cycles, and as clinically indicated. Correct any abnormality before starting therapy with KISQALI or the KISQALI FEMARA Co-Pack therapy.

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

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KISQALI® ribociclib 200 mg tablets

In addition to what you are used to from CoverMyMeds and Novartis Oncology Patient Support, now you can work on PA in parallel through CoverMyMeds

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

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

>80% KISQALI PAs are approved

2 DAYS Majority of claims are approved in 2 days

2 Specialty Pharmacies

- All Specialty Pharmacies can fill KISQALI
- 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.patient.novartisoncology.com/financial-assistance/pano/

Call the Specialty Pharmacy of your choice to get started

3 KISQALI CARE patient support | Patient Assistance Now Oncology

Assistance. Access. Answers.

- Case managers in insurance benefits, PA appeals, and clinical care can provide resources and support for navigating insurance coverage
- Enroll eligible patients in $0 Co-pay* and KISQALI Access Program*
- Field Reimbursement Managers keep you informed every step of the way
- Patients are automatically paired with a dedicated Patient Navigator

Download a Start Form at HCP.Novartis.com/Access to get started

ePA=electronic prior authorization; HCP=health care provider; PA=prior authorization.

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

Sample letters

If a patient is denied coverage, health care providers (HCPs) are required to explain their clinical rationale for prescribing KISQALI in a Letter of Appeal. This letter addresses each specific reason given for the denial. The health plan is likely to have a preferred formulary for the management of breast cancer, so the appeal will also need to demonstrate why the health plan's formulary is not the most appropriate treatment for this patient.

We have included sample Letters of Appeal and Medical Necessity, which address whether the patient is actively on breast cancer treatment or not. No matter the patient's treatment status, each letter should be submitted with a copy of the patient's relevant medical records and a Letter of Medical Necessity. 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). Avoid the use of KISQALI or the KISQALI FEMARA Co-Pack in patients who already have or who are at significant risk of developing QT prolongation, including patients with:

- long QT syndrome
- uncontrolled or significant cardiac disease including recent myocardial infarction, congestive heart failure, unstable angina, and bradyarrhythmias
- electrolyte abnormalities

Avoid using KISQALI or the KISQALI FEMARA Co-Pack with drugs known to prolong the QT interval and/or strong CYP3A inhibitors, as this may lead to prolongation of the QTcF interval.

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IMPORTANT SAFETY INFORMATION for KISQALI and KISQALI FEMARA Co-Pack

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Across clinical trials in patients with advanced or metastatic breast cancer treated with KISQALI in combination with an aromatase inhibitor or fulvestrant ("KISQALI treatment groups"), 1.2% of patients treated with KISQALI had ILD/pneumonitis of any grade, 0.3% had grade 3/4, and 0.1% had a fatal outcome. Additional cases of ILD/pneumonitis have been observed in the postmarketing setting, with fatalities reported.

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 treatment with KISQALI immediately and evaluate the patient. Permanently discontinue treatment with KISQALI in patients with recurrent symptomatic or severe 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. Consultation with a dermatologist is recommended.

If SCARs 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® (ribociclib) and the KISQALI® (ribociclib) FEMARA® (letrozole) Co-Pack have been shown to prolong the QT interval in a concentration-dependent manner. Based on the observed QT prolongation during treatment, KISQALI may require dose interruption, reduction, or discontinuation. In MONALEESA-2 and MONALEESA-7, in patients with advanced or metastatic breast cancer who received the combination of KISQALI plus an aromatase inhibitor, 7 of 574 patients (1%) had >500 ms postbaseline QTcF value, and 29 of 574 patients (5%) had a >60 ms increase from baseline in QTcF intervals. These electrocardiogram (ECG) changes were reversible with dose interruption and most occurred within the first 4 weeks of treatment. No cases of torsades de pointes were reported. In MONALEESA-2, on 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.

Assess ECG prior to initiation of treatment. Initiate treatment with KISQALI or the KISQALI FEMARA Co-Pack only in patients with QTcF values <450 ms. Repeat ECG at approximately Day 14 of the first cycle, at the beginning of the second cycle, and as clinically indicated. Monitor serum electrolytes (including potassium, calcium, phosphorus, and magnesium) prior to the initiation of treatment, at the beginning of each of the first 6 cycles, and as clinically indicated. Correct any abnormality before starting therapy with KISQALI or the KISQALI FEMARA Co-Pack therapy.

Avoid the use of KISQALI or the KISQALI FEMARA Co-Pack in patients who already have or who are at significant risk of developing QT prolongation, including patients with:

- long QT syndrome
- uncontrolled or significant cardiac disease including recent myocardial infarction, congestive heart failure, unstable angina, and bradyarrhythmias
- electrolyte abnormalities

Avoid using KISQALI or the KISQALI FEMARA Co-Pack with drugs known to prolong the QT interval and/or strong CYP3A inhibitors, as this may lead to prolongation of the QTcF interval.

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

Femara® (letrozole) 2.5 mg tablets

KISQALI® ribociclib 200 mg tablets

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

Hepatobiliary toxicity. Across KISQALI treatment groups, increases in transaminases were observed. In MONALEESA-2 and MONALEESA-7, grade 3/4 increases in alanine aminotransferase (ALT) (11% vs 2%) and aspartate aminotransferase (AST) (8% vs 2%) were reported in the KISQALI and placebo arms, respectively.

Among the patients who had grade ≥3 ALT/AST elevation, the median time to onset was 111 days and median time to resolution to grade ≤2 was 22 days for the KISQALI treatment groups.

In MONALEESA-2, concurrent elevations in ALT or AST greater than 3 times the upper limit of normal (ULN) and total bilirubin greater than 2 times the ULN, with normal alkaline phosphatase, in the absence of cholestasis occurred in 4 (1%) patients and all patients recovered after discontinuation of KISQALI. No cases occurred in MONALEESA-7.

Perform liver function tests (LFTs) before initiating therapy with KISQALI or the KISQALI FEMARA Co-Pack. 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. Recommendations for patients who have elevated AST/ALT grade ≥3 at baseline have not been established.

Neutropenia. Neutropenia was the most frequently reported adverse reaction (AR) (79%), and a grade 3/4 decrease in neutrophil count (based on laboratory findings) was reported in 66% of patients in the KISQALI treatment groups. Among the patients who had grade 2, 3, or 4 neutropenia, the median time to grade ≥2 was 16 days. The median time to resolution of grade ≥3 (to normalization or grade <3) was 15 days in the KISQALI treatment groups. Febrile neutropenia was reported in 2% of patients in the KISQALI treatment groups. Treatment discontinuation due to neutropenia was 1%.

Perform complete blood count (CBC) before initiating therapy with KISQALI or the KISQALI FEMARA Co-Pack. 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. In animal reproduction studies, administration of KISQALI to pregnant rats and rabbits during organogenesis caused embryo-fetal toxicities at maternal exposures that were 0.6 and 1.5 times the human clinical exposure, respectively, based on area under the curve. Letrozole caused embryo-fetal toxicities in rats and rabbits at maternal exposures that were below the maximum recommended human dose on a milligrams-per-square-meter basis. Advise pregnant women of the potential risk to a fetus. Advise women of reproductive potential to use effective contraception during therapy with KISQALI or the KISQALI FEMARA Co-Pack and for at least 3 weeks after the last dose.

Adverse reactions. In the pooled safety population of MONALEESA-2 and MONALEESA-7, most common (incidence ≥20%) ARs include infections, nausea, fatigue, diarrhea, headache, alopecia, vomiting, back pain, constipation, cough, rash, and abdominal pain.

Laboratory abnormalities. In the pooled safety population of MONALEESA-2 and MONALEESA-7, the most common laboratory abnormalities reported in the KISQALI arm (all grades, pooled incidence ≥20%) **were leukocytes decreased, neutrophils decreased, hemoglobin decreased, lymphocytes decreased, ALT increased, AST increased, platelets decreased, and creatinine increased.**

Please see accompanying full Prescribing Information for KISQALI and full Prescribing Information for the KISQALI FEMARA Co-Pack.

Femara® (letrozole) 2.5 mg tablets

KISQALI® ribociclib 200 mg tablets

One free treatment cycle to get started

KISQALI® ribociclib 200 mg tablets

Femara (letrozole) 2.5 mg tablets

RxBIN: 601341
RxPCN: OHS
RxGRP: [XXXXXXXX]
ID: [XXXXXXXX]

1 FREE TREATMENT CYCLE OF ANY ONE OF THE FOLLOWING:

a. KISQALI FEMARA Co-Pack
b. KISQALI® (ribociclib)
c. FEMARA® (letrozole)
d. letrozole
e. KISQALI + FEMARA
f. KISQALI + letrozole

One free treatment cycle of the KISQALI FEMARA Co-Pack is available for patients with a valid prescription for the KISQALI FEMARA Co-Pack. One free treatment cycle of KISQALI is available for patients with a valid prescription for KISQALI. One free treatment cycle of FEMARA is available for patients with a valid prescription for FEMARA (including generic letrozole), including for patients who have not been prescribed KISQALI or another Novartis product.

Please see accompanying full Prescribing Information for KISQALI and full Prescribing Information for KISQALI FEMARA Co-Pack.

- Patients are eligible to receive a 1-treatment-cycle supply of KISQALI, FEMARA, the KISQALI FEMARA Co-Pack, and/or generic letrozole **at no cost**
- No purchase required of KISQALI, FEMARA, the KISQALI FEMARA Co-Pack, and/or generic letrozole. This offer is available for patients with a valid prescription for KISQALI, FEMARA, the KISQALI FEMARA Co-Pack, and/or generic letrozole, including patients who have not been prescribed KISQALI or another Novartis product

Please see your sales representative for vouchers, or call 1-800-282-7630.
You can also download a voucher by visiting FreeTreatmentVoucher.com

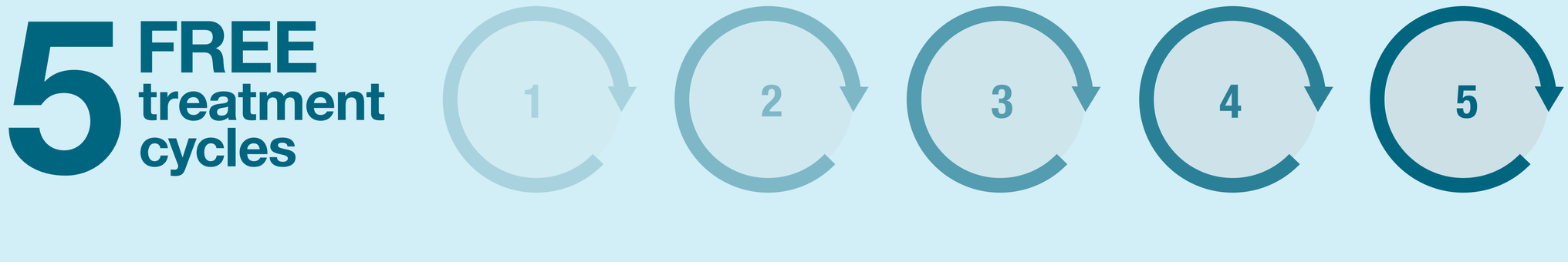
Please click here for Important Safety Information, and click here for full Prescribing Information.

Femara® (letrozole) 2.5 mg tablets

KISQALI® ribociclib 200 mg tablets

Up to 5 free treatment cycles for uninterrupted access

Through the KISQALI Access Program, commercially insured patients waiting for their coverage to take effect for KISQALI, FEMARA, the KISQALI FEMARA Co-Pack, and/or generic letrozole may be eligible for an additional supply of KISQALI that could continue for up to 5 treatment cycles.



To enroll eligible patients in this patient support service, submit a completed Novartis Patient Assistance Now Oncology (PANO) Service Request Form and select the KISQALI Access Program check box.

Follow this link to access the PANO Service Request Form

Limitations apply. Eligible patients must have commercial insurance, a completed Service Request Form, and be experiencing a delay in obtaining coverage for KISQALI. 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. No purchase necessary. Participation is not a guarantee of insurance coverage. Once coverage is approved, patients will no longer be eligible. Novartis Pharmaceuticals Corporation reserves the right to rescind, revoke, or amend this program without notice.

Patients may be eligible for immediate co-pay savings

NOVARTIS

Universal Co-pay Card

Eligible patients save on out-of-pocket costs

Tell your patients to visit
Copay.NovartisOncology.com
or call **1-877-577-7756.**

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

- Novartis will pay the remaining co-pay, up to $15,000 per calendar year, per product

- Limitations apply. This offer is only available to patients with private insurance. The Program is NOT AVAILABLE for patients who are enrolled in Medicare, Medicaid, or any other federal or state health care program. Use of this offer for FEMARA (or generic letrozole) does not require a KISQALI prescription. Offer is NOT valid for purchases of FEMARA ***only*** by California or Massachusetts residents. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full terms and conditions, visit CoPay.NovartisOncology.com or call 1-877-577-7756

Patients can find out if they are eligible to enroll in the Universal Co-pay Program by visiting Copay.NovartisOncology.com. Patients can also call 1-877-577-7756

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

A. Novartis is committed to helping patients get the Novartis medicines they need. Novartis Patient Assistance Now Oncology (PANO) team and our field Reimbursement Managers offer 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 case managers with private extensions whom you can contact directly for updates on your patient
- A combination of PANO case managers and/or field Reimbursement Managers are available to help, depending on the complexity of a patient's case

To learn more, visit: hcp.novartis.com/Access or call 1-800-282-7630

Q. What is the main type of coverage request required for KISQALI access?

A. Prior authorization (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	• 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) • Provide documentation of patient response to therapy if treatment with KISQALI was previously initiated	A complete and robust PA can help avoid or simplify any future coverage hurdles

95% of PA requests for KISQALI are approved during the initial authorization request

Q. What are other types of coverage communications that may be required for KISQALI?

A. Other types of coverage communications include Prior Authorization (PA) Appeal Letter, Formulary Exception Request, and Letter of Medical Necessity.

COVERAGE REQUEST	DESCRIPTION	HOW TO OBTAIN REQUIRED FORMS	PREPARING THE REQUEST	ADDITIONAL CONSIDERATIONS
PA Appeal Letter	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 all requested information • Always include a patient's **relevant medical records** and a **Letter of Medical Necessity** • Provide complete information, including the patient's menopausal status (if female) and clinical trial results (see pages 3-5 for more information) • 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		
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 menopausal status (if female) and clinical trial results for KISQALI (see pages 3-5 for more information) • **Include specific billing codes where appropriate** **Support your recommendations with the following:** • Patient history, diagnosis with HR+/HER2- advanced breast cancer, 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**	• 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

HER2-=human epidermal growth factor receptor 2-negative; HR+=hormone receptor-positive.

Select ICD-10 diagnostic codes for breast cancer[13]

The coding information provided below may assist you in completing the health plan's forms for KISQALI, may not represent all possible codes, and is for informational purposes only.

These codes are not all-inclusive. Coding may vary by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

FEMALE | **MALE**

ICD-10 Diagnostic Codes

LEFT BREAST		RIGHT BREAST	
CODE	**DESCRIPTION**	**CODE**	**DESCRIPTION**
C50.012	Malignant neoplasm of nipple and areola, left female breast	**C50.011**	Malignant neoplasm of nipple and areola, right female breast
C50.112	Malignant neoplasm of central portion, left female breast	**C50.111**	Malignant neoplasm of central portion, right female breast
C50.212	Malignant neoplasm of upper-inner quadrant, left female breast	**C50.211**	Malignant neoplasm of upper-inner quadrant, right female breast
C50.312	Malignant neoplasm of lower-inner quadrant, left female breast	**C50.311**	Malignant neoplasm of lower-inner quadrant, right female breast
C50.412	Malignant neoplasm of upper-outer quadrant, left female breast	**C50.411**	Malignant neoplasm of upper-outer quadrant, right female breast
C50.512	Malignant neoplasm of lower-outer quadrant, left female breast	**C50.511**	Malignant neoplasm of lower-outer quadrant, right female breast
C50.612	Malignant neoplasm of axillary tail, left female breast	**C50.611**	Malignant neoplasm of axillary tail, right female breast
C50.812	Malignant neoplasm of overlapping sites, left female breast	**C50.811**	Malignant neoplasm of overlapping sites, right female breast
C50.912	Malignant neoplasm of unspecified site, left female breast	**C50.911**	Malignant neoplasm of unspecified site, right female breast
D05.02	Lobular carcinoma in situ, left breast	**D05.01**	Lobular carcinoma in situ, right breast
D05.12	Intraductal carcinoma in situ, left breast	**D05.11**	Intraductal carcinoma in situ, right breast
D05.82	Other specified type of carcinoma in situ, left breast	**D05.81**	Other specified type of carcinoma in situ, right breast

Select ICD-10 diagnostic codes for breast cancer[13]

The coding information provided below may assist you in completing the health plan's forms for KISQALI, may not represent all possible codes, and is for informational purposes only.

These codes are not all-inclusive. Coding may vary by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

FEMALE		MALE	
ICD-10 Diagnostic Codes			
LEFT BREAST		**RIGHT BREAST**	
CODE	**DESCRIPTION**	**CODE**	**DESCRIPTION**
C50.022	Malignant neoplasm of nipple and areola, left male breast	**C50.021**	Malignant neoplasm of nipple and areola, right male breast
C50.122	Malignant neoplasm of central portion, left male breast	**C50.121**	Malignant neoplasm of central portion, right male breast
C50.222	Malignant neoplasm of upper-inner quadrant, left male breast	**C50.221**	Malignant neoplasm of upper-inner quadrant, right male breast
C50.322	Malignant neoplasm of lower-inner quadrant, left male breast	**C50.321**	Malignant neoplasm of lower-inner quadrant, right male breast
C50.422	Malignant neoplasm of upper-outer quadrant, left male breast	**C50.421**	Malignant neoplasm of upper-outer quadrant, right male breast
C50.522	Malignant neoplasm of lower-outer quadrant, left male breast	**C50.521**	Malignant neoplasm of lower-outer quadrant, right male breast
C50.622	Malignant neoplasm of axillary tail, left male breast	**C50.621**	Malignant neoplasm of axillary tail, right male breast
C50.822	Malignant neoplasm of overlapping sites, left male breast	**C50.821**	Malignant neoplasm of overlapping sites, right male breast
C50.922	Malignant neoplasm of unspecified site, left male breast	**C50.921**	Malignant neoplasm of unspecified site, right male breast
D05.02	Lobular carcinoma in situ, left breast	**D05.01**	Lobular carcinoma in situ, right breast
D05.12	Intraductal carcinoma in situ, left breast	**D05.11**	Intraductal carcinoma in situ, right breast
D05.82	Other specified type of carcinoma in situ, left breast	**D05.81**	Other specified type of carcinoma in situ, right breast

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