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 FREE Trial Offer here, and 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

NCCN CATEGORY 1 RECOMMENDATION

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

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]

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; 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	In the MONALEESA-2 clinical trial, postmenopausal women with HR+/HER2- aBC and no prior ET for advanced disease received KISQALI in combination with letrozole.
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. 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).
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

MONALEESA-2 is the only CDK4/6i trial to demonstrate a statistically significant OS advantage 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.

KISQALI® ribociclib 200 mg tablets

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	In the MONALEESA-3 clinical trial for KISQALI, postmenopausal women with HR+/HER2- mBC received KISQALI in combination with fulvestrant as a 1L therapy for advanced disease, or a 2L therapy after progression on ET.
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	For patients receiving KISQALI, at a median follow-up of 71 months (exploratory analysis), mOS 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). 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.

MONALEESA-3 demonstrated a statistically significant OS advantage in 1L and 2L postmenopausal patients with 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	In the MONALEESA-7 clinical trial for KISQALI, pre/perimenopausal women with HR+/HER2- mBC received KISQALI in combination with an NSAI and goserelin as a 1L therapy for advanced disease.
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 54 months (exploratory analysis*), mOS 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, 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	In the NATALEE clinical trial for KISQALI, adults with HR+/HER2- stage II and III eBC at high risk of recurrence received KISQALI in combination with an NSAI.
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). In an exploratory analysis, at a median follow-up of 44 months, with 603 iDFS events in the study (263 [10.3%] in the KISQALI arm and 340 [13.3%] in the NSAI-alone arm), iDFS at the 4-year landmark was 88.5% for KISQALI + NSAI vs 83.6% for NSAI alone **(absolute difference 4.9%);** there was a 28.5% relative reduction in the risk of an iDFS event; HR=0.715 (95% CI: 0.609-0.840).
DDFS*	With 460 DDFS (secondary end point) events in the study (204 [8%] in the KISQALI arm and 256 [10%] in the NSAI-alone arm), DDFS at the 3-year landmark was 92.9% for KISQALI + NSAI vs 90.2% for NSAI alone **(absolute difference 2.7%);** there was a 25.1% relative reduction in the risk of a DDFS event; HR=0.749 (95% CI: 0.623-0.900). With 551 DDFS events in the study (240 [9.4%] in the KISQALI arm and 311 [12.2%] in the NSAI-alone arm), DDFS at the 4-year landmark was 89.4%% for KISQALI + NSAI vs 84.9% for NSAI alone **(absolute difference 4.5%);** there was a 28.5% relative reduction in the risk of a DDFS event; HR=0.715 (95% CI: 0.604-0.847).
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. No new safety signals were observed with further follow up.

KISQALI consistently reduced the threat of recurrence in the broadest range of patients, including those with grade 1 disease or no nodal involvement[3,4]

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 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 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 unique benefits of KISQALI® (ribociclib)

OS 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.[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

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

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

Click here for MONALEESA-2 data

☐ In postmenopausal women, in combination with fulvestrant, as a 1L therapy for advanced disease or as a 2L therapy after progression on ET[1]:
- Over 5.5 years mOS[12]

Click here for MONALEESA-3 data

☐ In premenopausal women, in combination with an NSAI and goserelin, as a 1L therapy[1]:
- Nearly 5 years mOS[13]

Click here for MONALEESA-7 data

Only KISQALI—a proven risk reduction in invasive and distant diseases for patients with stage II and III eBC via phase III trial[3]

☐ In adults with HR+/HER2- stage II and III eBC in combination with an NSAI:
- 25.1% relative reduction in the risk of invasive disease at 3 years and 28.5% relative reduction in the risk of invasive disease at 4 years
- Absolute DDFS benefit of 2.7% at 3 years and 4.5% at 4 years

Click here for NATALEE 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. *J Clin Oncol*. 2018;36(24):2465-2472. Click here to access the full publication.
- 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.

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[1]

FDA=US Food and Drug Administration.

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®)

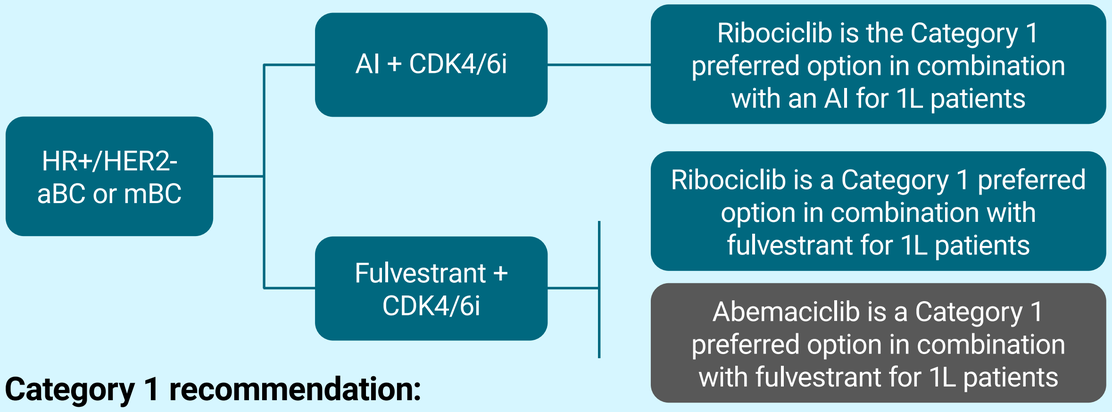
Consider citing the most current NCCN Guidelines® for Breast Cancer

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

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



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

- ☐ 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:
long QT syndrome

- 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

>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.novartis.com/us-en/patients-and-caregivers/novartis-patient-support-oncology

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.

Free Trial Offer*

With our Free Trial Offer,* patients can start on KISQALI® (ribociclib) today at no cost.

Novartis Patient Support™

FREE TRIAL OFFER

1 treatment cycle

KISQALI® ribociclib 200 mg tablets

BIN **601341**
GRP OH7128091
PCN **OHS**
Rx ID L31109756072

How does the Free Trial Offer* work?

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

Download the Free Trial Offer or reach out to your Dedicated Novartis Associate Director, Access & Reimbursement (ADAR) for questions

***No purchase required.** This free trial is not health insurance. Void where prohibited by law. Product dispensed pursuant to terms and conditions of voucher. Valid only in the US and Puerto Rico. For Massachusetts residents, offer is valid for one of the following: the KISQALI FEMARA Co-Pack or KISQALI and/or generic letrozole. Claims shall not be submitted to any public or private third-party payer or any federal or state health care program for reimbursement. Offer not valid if reproduced or submitted to any other payer. It is illegal for any person to sell, purchase or trade, or offer to sell, purchase or trade, or to counterfeit, this voucher. Prescriber ID# required on prescription. This is the property of Novartis Pharmaceuticals Corporation and must be returned upon request. Novartis Pharmaceuticals Corporation reserves the right to rescind, revoke, or amend this offer without notice.

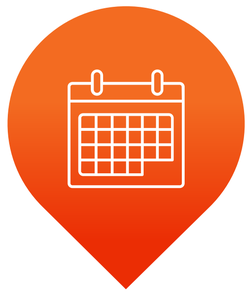
Please click here for Important Safety Information, and click here for full Prescribing Information for KISQALI.

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.



Patients can receive up to 5 free treatment cycles of KISQALI.

Privately 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 patient's coverage status is determined, Novartis Patient Support will help transition 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

***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.*

Novartis will pay the remaining Co-Pay, up to $15,000 per calendar year, per product.*

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.

***Limitations apply.** Valid only for those with private insurance. The Program includes the Co-Pay Plus offer, Plus Card (if applicable), and Rebate, with a combined annual limit up to $15,000. Patient is responsible for any costs once limit is reached in a calendar year. Program not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, (iii) where the patient's insurance plan reimburses for the entire cost of the drug, or (iv) where product is not covered by patient's insurance. The value of this program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Program is not valid where prohibited by law. Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the United States and Puerto Rico. This Program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

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**

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® (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 inlcude:
			  ◦ KISQALI is the only CDK4/6i with proven 1L OS benefit in mBC
			  ◦ KISQALI is the only CDK4/6i indicated for stage II eBC
			  ◦ 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 3-5 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

Select ICD-10 diagnostic codes for BC[19]

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 HCP 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 BC[19] (continued)

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 HCP 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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