Novartis Patient Support™

Potential *ICD-10-CM* Diagnosis Codes for KISQALI

We know that navigating insurance and reimbursement can be a challenge. Novartis Patient Support is by your side to help throughout the process.

This guide provides an overview of International Classification of Diseases, 10th Revision, Clinical Modification *(ICD-10-CM)* diagnosis codes for KISQALI.

- Review the health plan's guidance to ensure appropriate codes are selected based on a patient's medical record
- Keep in mind that some health plans may require both primary and secondary codes

Examples of potential codes that may be relevant for KISQALI include:

Primary Diagnosis Codes

ICD-Diagnostic Codes:			
FEMALE LEFT BREAST CODE	**DESCRIPTION**	**FEMALE RIGHT BREAST 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

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Potential *ICD-10-CM* Diagnosis Codes for KISQALI (continued)

Primary Diagnosis Codes (continued)

ICD-Diagnostic Codes:			
MALE LEFT BREAST CODE	**DESCRIPTION**	**MALE RIGHT BREAST 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

The codes listed above are provided for educational purposes only and are not a guarantee of coverage or reimbursement. 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.

Questions?

Reach out to your KISQALI Associate Director, Access & Reimbursement (ADAR), call Novartis Patient Support at **866-433-8000**, Monday-Friday, 8:00 AM-8:00 PM ET, excluding holidays, or go to **www.kisqali-hcp.com**.

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Potential *ICD-10-CM* Diagnosis Codes for KISQALI (continued)

INDICATIONS

KISQALI is indicated:

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

IMPORTANT SAFETY INFORMATION

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

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

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

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

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

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

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

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Potential *ICD-10-CM* Diagnosis Codes for KISQALI (continued)

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

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

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

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

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

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

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

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

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

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Potential *ICD-10-CM* Diagnosis Codes for KISQALI (continued)

Increased QT prolongation with concomitant use of tamoxifen. (cont)
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.

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Potential *ICD-10-CM* Diagnosis Codes for KISQALI (continued)

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.**

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KISQALI® ribociclib 200 mg tablets

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