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 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; or
- fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men.

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"), 1.6% of patients treated with KISQALI 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 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 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. Based on the observed QT prolongation during treatment, KISQALI may require dose interruption, reduction, or discontinuation. Across KISQALI treatment groups, 15 of 1054 patients (1.4%) had >500 ms postbaseline QTcF value, and 61 of 1054 (6%) had a >60 ms increase from baseline in QTcF intervals.

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

QT interval prolongation (cont). 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 or MONALEESA-3.

Assess ECG prior to initiation of treatment. Initiate treatment with KISQALI 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.

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

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 6/90 (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.

Hepatobiliary toxicity. Across KISQALI treatment groups, increases in transaminases were observed. Across all trials, grade 3/4 increases in alanine aminotransferase (ALT) (11% vs 2.1%) 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 92 days and median time to resolution to grade ≤2 was 21 days for the KISQALI treatment groups.

In MONALEESA-2 and MONALEESA-3, 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 6 (1%) patients and all patients recovered after discontinuation of KISQALI. No cases occurred in MONALEESA-7.

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Hepatobiliary toxicity (cont). Perform liver function tests (LFTs) before initiating therapy with KISQALI. Monitor LFTsevery 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. Across KISQALI treatment groups neutropenia was the most frequently reported adverse reaction (AR) (75%), and a grade 3/4 decrease in neutrophil count (based on laboratory findings) was reported in 62% 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 17 days. The median time to resolution of grade ≥3 (to normalization or grade <3) was 12 days in the KISQALI treatment groups. Febrile neutropenia was reported in 1.7% of patients in the KISQALI treatment groups. Treatment discontinuation due to neutropenia was 1%.

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. 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. 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. 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 see accompanying full Prescribing Information.

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KISQALI® ribociclib 200 mg tablets

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