KISQALI HR+ HER2- Stage II and Stage III Early Breast Cancer EHR Considerations Checklist

KISQALI is approved for HR+ HER2- stage II and stage III early breast cancer indications. Below are considerations for KISQALI configuration within your EHR.

1 ☑ Ensure KISQALI **drug defaults** and **medication records** are correct for HR+ HER2- Stage II and Stage III early breast cancer: NDC 0078-0867-42 (400 mg daily dose for 3 weeks on, 1 week off)

Consider embedding co-pay card link into medication record:

https://copay.novartisoncology.com/

2 ☑ Update all applicable **treatment plans/protocols** for HR+ HER2- eBC stage II and stage III with KISQALI (ribociclib) and KISQALI monitoring requirements.

Consider leveraging CDS to ensure monitoring requirements are met.

Assessments Checklist

Please click the relevant EHR below to access on the KISQALI website:

Epic

iKnowMed

Oracle Cerner

OncoEMR

CDS=clinical decision support; eBC=early breast cancer; EHR=electronic health record; HER2=human epidermal growth factor receptor 2; HR=hormone receptor; NDC=national drug code.

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.

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).

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 KISQALI in patients with severe ILD/pneumonitis or any recurrent symptomatic ILD/pneumonitis.

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Please see below for an illustrative example of a protocol

Pre-Treatment Cycle - Perform, 1 time,. Length: 28 days.
Day 1 - Perform 1 time on day 1 of the cycle. Day length: 1 day. Research tolerance: -0/+0 days.
ONCBCN OP APPOINTMENT REQUEST (CLINIC MD/AP & INFUSION)
Clinic Visit Appointment Request, Schedule appointment at most 0 days before or at most 0 days after Schedule for: Established Patient With provider type: MD or Advanced Practitioner Unfusion Room Appointment Appointment Request, Schedule appointment at most 0 days before or at most 0 days after
ONCBCN OP APPOINTMENT REQUEST (PHARMACIST FOLLOW UP TELEVISIT S+7 (for testing)
Pharmacist Visit Appointment Request, Schedule appointment at most 0 days before or at most 0 days after
ONCBON OP LABS (CBC W ANC/OMP)
ECG 12 lead Pre-Procedure, Expected: S, Expires: S+366 Physician communication Additional monitoring may be required as clinically indicated (select appropriate Order, Order Set, or Smart Set as needed). KISQALI should be initiated in patients with QTcF <450ms. In case of QTcF prolongation during therapy, more frequent monitoring is recommended.
FNR LOW PROVIDER COMMUNICATION
OP TREATMENT CONDITIONS (ANC < 1,000 / T. BILI > 2X ULN / CRCL < 30ML/MIN / AST/ALT>-3XULN /QTC>480)
ribociclib (KISQALI) 400 mg/day (200 mg x 2) Tab Oral Chemotherapy, Oral, starting S
Day 15 - Perform 1 time on day 15 of the cycle. Day length: 1 day. Research tolerance: -0/+0 days.
ONCBCN OP APPOINTMENT REQUEST (CLINIC MD/AP & INFUSION)
ONCBCN OP LABS (CBC W ANC/OMP)
PROVIDER COMMUNICATION RIBOCICLIB C1 D15 / C2 D1
FR LOW PROVIDER COMMUNICATION
OP TREATMENT CONDITIONS (ANC < 1,000 / T. BILI > 2X ULN / CRCL < 30ML/MIN / AST/ALT>3XULN / QTC>480)
FULVESTRANT 500 MG IM ONCE
HYPERSENSITIVITY REACTION STANDING ORDERS
Cycle 2 - Perform: 1 time. Length: 28 days.
Day 1 - Perform 1 time on day 1 of the cycle. Day length: 1 day. Research tolerance: -0/+0 days.
Day 15 - Perform 1 time on day 15 of the cycle. Day length: 1 day. Research tolerance: -0/40 days.

This image is intended for illustrative purposes only.

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.

IIf 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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IMPORTANT SAFETY INFORMATION (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.

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, 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%).

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.

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IMPORTANT SAFETY INFORMATION (continued)

Neutropenia (continued). 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. 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.**

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