ETCAMAH®
camizestrant
75 mg tablets

ETCAMAH Epic® EHR System Guide

Tipsheet for Patient Lists, Order Sets, and Incorporating *ESR1*m Testing Into Treatment Calendars

ETCAMAH introduces a new treatment paradigm in combination with a CDK4/6 inhibitor for HR-positive, HER2-negative locally advanced or metastatic breast cancer upon detection of *ESR1* mutation during aromatase inhibitor and CDK4/6 inhibitor therapy. It is important to update your Epic EHR system today to stay up to date with the latest clinical advancements in locally advanced and metastatic breast cancer.

SELECT SAFETY INFORMATION INCLUDING BOXED WARNING ABOUT ETCAMAH® (camizestrant)

WARNING: ARRHYTHMIA RISK WITH CONCOMITANT USE OF QTc INTERVAL PROLONGING DRUGS

ETCAMAH in combination with ribociclib, a QTc interval prolonging drug and a strong CYP3A inhibitor, or in combination with other QTc interval prolonging drugs, can increase the risk of Torsades de Pointes (TdP), other ventricular arrhythmias, and sudden death.

Avoid concomitant use of ETCAMAH with products (other than ribociclib) known to prolong the QTc interval and/or have a known risk of TdP. If concomitant use with other products cannot be avoided, monitor the QTc interval more frequently.

Obtain electrocardiogram (ECG) prior to initiation and monitor heart rate (HR) and QTc interval during treatment. Assess and correct electrolyte abnormalities prior to initiation and during treatment. Withhold ETCAMAH until resolution of QTc interval prolongation and resume or permanently discontinue ETCAMAH based on severity.

INDICATION

ETCAMAH in combination with a CDK4/6 inhibitor (abemaciclib, palbociclib, or ribociclib) is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer upon detection of *ESR1* mutation during aromatase inhibitor and CDK4/6 inhibitor therapy, based on an FDA-authorized test.

This indication is approved under accelerated approval based on progression-free survival as measured from detection of *ESR1* mutation. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

SELECT SAFETY INFORMATION ABOUT ETCAMAH® (CAMIZESTRANT)

WARNING AND PRECAUTIONS

QTc Interval Prolongation: ETCAMAH in combination with a CDK4/6 inhibitor (CDK4/6i) is associated with QTc interval prolongation.

CDK4/6i = cyclin-dependent kinase 4/6 inhibitor; EHR = electronic health record; *ESR1* = estrogen receptor 1 gene; *ESR1*m = estrogen receptor 1 mutation; FDA = US Food and Drug Administration; HER2 = human epidermal growth factor receptor 2; HR = hormone receptor.

Please see additional Important Safety Information on pages 32 to 34 and full Prescribing Information, including Boxed WARNING, and Patient Information for ETCAMAH.

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1L = first-line; AI = aromatase inhibitor.

Suggested Instructions to Identify Patients With HR-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During AI and CDK4/6i Therapy, Based on an FDA-Authorized Test, or Those Eligible for *ESR1*m Testing

This document is intended to provide health systems with instructions to create a patient list in the Epic® EHR system to identify certain adult patients with HR-positive, HER2-negative, locally advanced or metastatic breast cancer upon detection of *ESR1* mutation (*ESR1*m) during aromatase inhibitor and CDK4/6 inhibitor therapy, based on an FDA-authorized test, or those who may be eligible for *ESR1*m testing. This guide provides instructions for the following 3 scenarios:

- Adult patients with HR-positive/HER2-negative locally advanced or metastatic breast cancer AND aromatase inhibitor and CDK4/6 inhibitor therapy AND no *ESR1*m test ordered. For patients identified on this list, practitioners may consider ordering an *ESR1*m test
- Adult patients with HR-positive/HER2-negative locally advanced or metastatic breast cancer AND aromatase inhibitor and CDK4/6 inhibitor therapy AND *ESR1*m test ordered BUT no structured result for *ESR1*m test available in the EHR. For patients identified on this list, a manual chart view should be considered to determine *ESR1*m test result and appropriateness for ETCAMAH or continued monitoring for *ESR1*m emergence
- Adult patients with HR-positive/HER2-negative locally advanced or metastatic breast cancer AND aromatase inhibitor and CDK4/6 inhibitor therapy AND *ESR1*m test ordered WITH the result available in a structured field in the EHR. For patients identified on this list, practitioners may consider appropriateness for ETCAMAH or continued monitoring for *ESR1*m emergence

This guide is for the Epic EHR system and is not appropriate for other conditions, treatments, or therapeutic areas or for other EHR systems.

The process outlined in this document is variable, and not all steps will apply to every organization. Any steps or settings that are not part of an organization's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The organization is solely responsible for implementing, testing, monitoring, and the ongoing operation of any EHR tools.

Diagnoses:

HR-Positive/HER2-Negative Diagnoses[1]:

- The single code of Z17.411: Hormone Receptor (HR)-positive/Human Epidermal Growth Factor Receptor 2 (HER2)-negative status (this code represents a combination of the below 2 codes) OR
- Z17.0: HR-positive status AND Z17.32: HER2-negative status

Breast Cancer Diagnoses:

- Breast Cancer: See Appendix A
- Codes Indicating Metastases: See Appendix B

Suggested Instructions to Identify Patients With HR-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During AI and CDK4/6i Therapy, Based on an FDA-Authorized Test, or Those Eligible for *ESR1*m Testing (cont'd)

Medications:

- Aromatase inhibitor and CDK4/6 inhibitor therapy, to be identified by each organization by medication grouper, therapeutic class, or individual medications

Procedure(s):

- FDA-authorized test for *ESR1*m detection, to be identified by organization-specific coding practices

Note: Consider running the report on a regular basis. Once the initial report has been created, it can be saved for future use and subsequent reports can be rerun. Running reports over time allows for the identification of new patients meeting the inclusion criteria.

Suggested Instructions to Identify Patients With HR-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During AI and CDK4/6i Therapy, Based on an FDA-Authorized Test, or Those Eligible for *ESR1*m Testing (cont'd)

Consider **Reporting Workbench** or **SlicerDicer** to create the patient list. Consult your organization if administrative user rights are required to access the reporting solutions.

Review documentation practices in the EHR when considering creating the patient report. Two options are provided in the instructions: Reporting Workbench and SlicerDicer. Depending on availability, consider the preferred reporting tool to complete the patient report. SlicerDicer may not always include a SmartData or Staging search criterion.

Option 1: Reporting Workbench–Using the Generic Criteria or Oncology Report Template

1. Access **Reporting Workbench** (click the Epic® logo > Reports > My Reports)
2. Navigate to the Library tab from the Reports menu
3. Enter "generic criteria" in the search field and click Search
4. Select the **Find Patients** - Generic Criteria report or Oncology Generic Criteria and click New
   - If using the Oncology Generic Criteria template, some criteria may appear by default depending on organizational settings. If the "Which Plans?" question appears in the criteria list, select "Active treatment or therapy plans"
5. In the **Report Settings** window, select the Criteria tab and add the first criterion to the query
6. In the **Find Criteria** search field, enter "living" and select the Patient Living Status and set the status to "Alive"
7. In the **Find Criteria** search field, enter "age" and select the Age in years criteria and set the age range to 18 years and older
8. In the **Find Criteria** field, enter "diagnosis" and select the Diagnosis by Code criterion
9. Enter and select the diagnosis code(s) for HR-positive/HER2-negative status. This can vary by organization and may include the following:
   a. A single ICD-10 code of Z17.411 OR
   b. Two separate ICD-10 codes:
      i. Z17.0 to indicate hormone receptor (HR)-positive status AND Z17.32 to indicate human epidermal growth factor receptor 2 (HER2)-negative status
10. Enter and select the diagnosis codes for locally advanced or metastatic breast cancer
    - Due to the number of codes used to designate these statuses, please refer to Appendix A for the list of recommended ICD-10 codes for identifying breast cancer and to Appendix B for the list of recommended ICD-10 codes for identifying metastases

ICD-10 = International Classification of Diseases, 10th Revision.

Suggested Instructions to Identify Patients With HR-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During AI and CDK4/6i Therapy, Based on an FDA-Authorized Test, or Those Eligible for *ESR1*m Testing (cont'd)

11. In the **Find Criteria** search field, enter "medication" – the selection from the list that is displayed will vary by organization and can include the following options. Regardless of the option selected below, you will also need to ensure you either add criteria to only pull patients who have at least 6 months of CDK4/6i therapy into the report OR apply a filter after the report is run to select patients with at least 6 months of CDK4/6i therapy to consider for *ESR1*m testing. If using the Oncology Generic Criteria template, you can add the "Plan: Treatment start date" criteria to further refine the results
    a. Select "Meds: current, by grouper" if your organization has aromatase inhibitor and CDK4/6 inhibitor therapy built as a med grouper within Epic®. Then, select the appropriate grouper used at your organization to identify aromatase inhibitor and CDK4/6 inhibitor therapy OR
    b. Select "med from therapeutic class" if your organization does not have a grouper built for these medications. Then, select the therapeutic class that contains aromatase inhibitor and CDK4/6 inhibitor therapy OR
    c. Select "medication history by medication" and select each of the aromatase inhibitor and CDK4/6 inhibitor therapies available at your organization. You may need to check with pharmacy for a complete listing of available agents

Steps 1-11 above apply to all patient identification scenarios. The following steps are specific to the 3 scenarios outlined in the "Overview and Limitations" section. Note that Steps 1-11 are the foundation for the report and then should be combined with the following scenarios as appropriate based on your organization's workflow.

Suggested Instructions to Identify Patients With HR-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During AI and CDK4/6i Therapy, Based on an FDA-Authorized Test, or Those Eligible for *ESR1*m Testing (cont'd)

Additional Steps to Identify Patients With No *ESR1*m Test

12. **How you determine if a patient had an FDA-authorized test that included the *ESR1*m biomarker may vary by organization and can include the following:**
    a. In the **Find Criteria** search field, enter "procedure" and select "procedures." Next, you can enter the billing CPT code or name of the FDA-authorized test for *ESR1*m detection, to be identified by organization-specific coding practices OR
    b. In the **Find Criteria** search field, enter "order" and select "orders." Next, you can either enter the billing CPT code or name of the FDA-authorized test for *ESR1*m detection, to be identified by organization-specific coding practices OR
    c. In the **Find Criteria** search field, enter "charge" and select "charge code." Next, enter the charge code for the FDA-authorized test for *ESR1*m detection, to be identified by organization-specific coding practices
13. Setting the logic:
    – Set the logic to include patient living status AND age AND BOTH HR-positive/HER2-negative status AND at least 1 of the locally advanced OR metastatic breast cancer diagnoses AND existence of aromatase inhibitor and CDK4/6 inhibitor therapy for at least 6 months. In the Criterion Logic for the Procedure, Order, or Charge Code for the *ESR1*m test, choose a logic type of "Custom" and use an "AND NOT" statement to ensure the patient list meets all criteria for patients without the existence of the FDA-authorized test for *ESR1*m
14. Select the **Display** tab to set all display columns for the report. Search for any display information in the Available Columns pane. Select all desired columns and click the right arrow to drag to the Selected Columns pane
15. In the **Display** tab, navigate to the Detailed Views section and set additional information displays. Consider adding the current and past medications, springboard and cancer stage summary views
16. In the **General** tab, enter the desired Report Name (eg, **"Patients to Review for *ESR1*m Testing Appropriateness"** or **"Patients With No *ESR1*m Test Ordered"**) and a Description. Results can be shared with selected users or pools
17. Click **Save** and **Run** to create the patient list. The list will display all patients matching the criteria

Note: The above steps only consider patients for whom an *ESR1*m test has not been ordered or performed at any point. This list is to be used to consider patients for whom an *ESR1*m test may be appropriate.

CPT = Current Procedural Terminology.

Suggested Instructions to Identify Patients With HR-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During AI and CDK4/6i Therapy, Based on an FDA-Authorized Test, or Those Eligible for *ESR1*m Testing (cont'd)

Additional Steps to Identify Patients With *ESR1*m Test but No Structured Result

12. **How you determine if a patient had an FDA-authorized test that included the *ESR1*m biomarker may vary by organization and can include the following:**
    a. In the **Find Criteria** search field, enter "procedure" and select "procedures." Next, you can either enter the billing CPT code or name of the FDA-authorized test for *ESR1*m detection, to be identified by organization-specific coding practices OR
    b. In the **Find Criteria** search field, enter "order" and select "orders." Next, you can either enter the billing CPT code or name of the FDA-authorized test for *ESR1*m detection, to be identified by organization-specific coding practices OR
    c. In the **Find Criteria** search field, enter "charge" and select "charge code." Next, enter the charge code for the FDA-authorized test for *ESR1*m detection, to be identified by organization-specific coding practices
13. Setting the logic:
    – Set the logic to include patient living status AND age AND BOTH HR-positive/HER2-negative status AND at least 1 of the locally advanced OR metastatic breast cancer diagnoses AND existence of aromatase inhibitor and CDK4/6 inhibitor therapy AND existence of the FDA-authorized test for *ESR1*m
14. Select the **Display** tab to set all display columns for the report. Search for any display information in the Available Columns pane. Select all desired columns and click the right arrow to drag to the Selected Columns pane
15. In the **Display** tab, navigate to the Detailed Views section and set additional information displays. Consider adding the current and past medications, springboard and cancer stage summary views
16. In the **General** tab, enter the desired Report Name (eg, "**Patients Requiring Chart Review to Determine ETCAMAH Eligibility"** or **"Patients w/ HR+/HER2- mBC and *ESR1*m Results Requiring Chart Review"**) and a Description. Results can be shared with selected users or pools
17. Click **Save** and **Run** to create the patient list. The list will display all patients matching the criteria

Note: The above steps do not consider the results of the *ESR1*m test due to *ESR1*m test results not typically being stored in discrete fields within the EHR. For the patients who are listed on the output of the report, the recommendation is a manual chart review of *ESR1*m status to determine eligibility. If, upon review, an *ESR1* mutation is detected, these patients could be considered for ETCAMAH. In addition, for patients who are identified as having an *ESR1* mutation upon chart review, the HCP should also consider discontinuing any further *ESR1*m testing if any recurring orders remain active for testing. If, upon review, an *ESR1* mutation is not detected, these patients may be eligible for routine monitoring for *ESR1*m emergence ahead of disease progression. For organizations where *ESR1*m biomarker test results are stored as discrete fields in the EHR, proceed to the following additional steps.

HCP = health care professional; mBC = metastatic breast cancer.

Suggested Instructions to Identify Patients With HR-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During AI and CDK4/6i Therapy, Based on an FDA-Authorized Test, or Those Eligible for *ESR1*m Testing (cont'd)

Additional Steps to Identify Patients With *ESR1*m Test With Structured Results

12. **In the Find Criteria search field, enter "genetic" or "genomic" and select "Genomic Variant Results." Next enter the billing CPT code or name of the FDA-authorized test for *ESR1*m detection, to be identified by organization-specific coding practices and select the appropriate test**
    - **Depending on the build at your organization, you may also have the ability to select options related to the *ESR1*m result pertaining to Variant Classification (Likely Benign, Pathogenic, Tier 1, Tier 2, etc), Assessment (Detected, Indeterminate, Negative, Not Detected), AA Change, DNA Change**
13. Setting the logic:
    - Set the logic to include patient living status AND age AND BOTH HR-positive/HER2-negative status AND at least 1 of the locally advanced OR metastatic breast cancer diagnoses AND existence of aromatase inhibitor and CDK4/6 inhibitor therapy AND existence of the *ESR1*m test result for *ESR1*
14. Select the **Display** tab to set all display columns for the report. Search for any display information in the Available Columns pane. Select all desired columns and click the right arrow to drag to the Selected Columns pane. Be sure to include columns that have the desired result information needed
15. In the **Display** tab, navigate to the Detailed Views section and set additional information displays. Consider adding the current and past medications, springboard and cancer stage summary views
16. In the **General** tab, enter the desired Report Name (eg, **"Patients With *ESR1*m Results to Consider for ETCAMAH Eligibility"** or **"Patients w/ HR+/HER2- mBC and *ESR1*m Results to Consider for ETCAMAH Eligibility"**) and a Description. Results can be shared with selected users or pools
17. Click **Save** and **Run** to create the patient list. The list will display all patients matching the criteria

Note: While the above steps do consider *ESR1*m test results stored in discrete fields, depending on workflow for incorporating external results at your organization, you may still consider a manual chart review to confirm results. The above list can be filtered to display patients with the actionable *ESR1* mutation(s) to consider for ETCAMAH. For patients who are identified as having an *ESR1* mutation, the HCP should also consider discontinuing any further *ESR1*m testing if any recurring orders remain active for testing. When no *ESR1* mutation is detected, these patients may be eligible for routine monitoring for *ESR1*m emergence ahead of disease progression.

Suggested Instructions to Identify Patients With HR-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During AI and CDK4/6i Therapy, Based on an FDA-Authorized Test, or Those Eligible for *ESR1*m Testing (cont'd)

Option 2: SlicerDicer

1. Access **SlicerDicer** (click the Epic® logo > Reports > SlicerDicer)
2. Depending on availability, select the **Patients** or **Patients With Cancer** data model (the number in the data model box represents the base population and number of records in the data model)
3. In the right-hand column, select the desired patient base, eg, "All Patients" (Note: First-time users of SlicerDicer may see a tutorial prompted during initial use. Complete the tutorial and continue with the steps described in this resource)
4. In the **Search** for criteria field, enter status. Alternatively, the + Browse button can be used too. When using the + Browse button, a new screen will display where the filter criterion and inclusion/exclusion status can be selected
5. Select the Patient Living Status criterion and set to Alive
6. In the **Search** for criteria field, enter age
7. Select the Age in years criterion and set the age range to 18 years and older
8. In the **Search** for criteria field, enter diagnosis
9. Select the Diagnosis (ICD) criteria
10. Enter the Diagnosis Codes of Z17.411 OR (Z17.0 AND Z17.32) depending on organizational coding
11. Enter the Diagnosis Codes for breast cancer found in Appendix A and the Diagnosis Codes that indicate metastases found in Appendix B
12. In the **Search** for criteria field, enter medication – the selection from the list that is displayed will vary by organization and can include the following options:
    a. Select "med from grouper" if your organization has aromatase inhibitor and CDK4/6 inhibitor therapy built as a med grouper within Epic. Then select the appropriate grouper used at your organization to identify aromatase inhibitor and CDK4/6 inhibitor therapy OR
    b. Select "med from therapeutic class" if your organization does not have a grouper built for these medications. Then select the therapeutic class that contains aromatase inhibitor and CDK4/6 inhibitor therapy OR
    c. Select "medications" and select each of the aromatase inhibitor and CDK4/6 inhibitor therapies available at your organization. You may need to check with pharmacy for a complete listing of available agents

Steps 1-12 above apply to all patient identification scenarios. The following steps are specific to the 3 scenarios outlined in the "Overview and Limitations" section. Note that steps 1-12 are the foundation for the report and then should be combined with the following scenarios as appropriate based on your organization's workflow.

Suggested Instructions to Identify Patients With HR-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During AI and CDK4/6i Therapy, Based on an FDA-Authorized Test, or Those Eligible for *ESR1*m Testing (cont'd)

Additional Steps to Identify Patients With No *ESR1*m Test

13. **How you determine if a patient had an FDA-authorized test that included the *ESR1*m biomarker may vary by organization and can include the following:**
    a. In the **Search for Criteria** field, enter "procedure" and select "procedures." Next, you can either enter the billing CPT code or name of the FDA-authorized test for *ESR1*m detection, to be identified by organization-specific coding practices OR
    b. In the **Search for Criteria** field, enter "order" and select "orders." Next, you can either enter the billing CPT code or name of the FDA-authorized test for *ESR1*m detection, to be identified by organization-specific coding practices OR
    c. In the **Search for Criteria** field, enter "charge" and select "charge code." Next, enter the charge code for the FDA-authorized test for *ESR1*m detection, to be identified by organization-specific coding practices
14. Setting the logic:
    – Set the logic to include patient living status AND age AND BOTH HR-positive/HER2-negative status AND at least 1 of the locally advanced OR metastatic breast cancer diagnoses AND existence of aromatase inhibitor and CDK4/6 inhibitor therapy AND NOT existence of *ESR1* order, procedure, or charge code to ensure the patient list meets all criteria for patients without the existence of the FDA-authorized test for *ESR1*m
15. Click the last icon with the detail table in the Visual Option section to see the query results
16. The results can be exported to Reporting Workbench by right clicking the bar with the patient results and selecting Show Slice in Reporting Workbench
17. In **Reporting Workbench**, select the **Display** tab to set all display columns for the report. Search for any display information in the Available Columns pane. Select all desired columns and click the right arrow to drag to the Selected Columns pane
18. In the **General** tab, enter the desired Report Name (eg **"Patients to Review for *ESR1*m Testing Appropriateness"** or **"Patients With No *ESR1*m Test Ordered"**) and a Description. Results can be shared with selected users or pools
19. Click **Save** and **Run** to create the patient list. The list will display all patients matching the criteria

Note: The above steps only consider patients for whom an *ESR1*m test has not been ordered or performed. This list is to be used to consider patients for whom an *ESR1*m test may be appropriate.

Suggested Instructions to Identify Patients With HR-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During AI and CDK4/6i Therapy, Based on an FDA-Authorized Test, or Those Eligible for *ESR1*m Testing (cont'd)

Additional Steps to Identify Patients With *ESR1*m Test but No Structured Result

13. **How you determine if a patient had an FDA-authorized test that included the *ESR1*m biomarker may vary by organization and can include the following:**

    In the **Search for Criteria** field, enter "procedure" and select "procedures." Next, you can either enter the billing CPT code or name of the FDA-authorized test for *ESR1*m detection, to be identified by organization-specific coding practices OR

    In the **Search for Criteria** field, enter "order" and select "orders." Next, you can either enter the billing CPT code or name of the FDA-authorized test for *ESR1*m detection, to be identified by organization-specific coding practices OR

    In the **Search for Criteria** field, enter "charge" and select "charge code." Next, enter the charge code for the FDA-authorized test for *ESR1*m detection, to be identified by organization-specific coding practices

14. Setting the logic:
    - Set the logic to include patient living status AND age AND BOTH HR-positive/HER2-negative status AND at least 1 of the locally advanced OR metastatic breast cancer diagnoses AND existence of aromatase inhibitor and CDK4/6 inhibitor therapy AND existence of *ESR1* order, procedure, or charge code
15. Click the last icon with the detail table in the Visual Option section to see the query results
16. The results can be exported to Reporting Workbench by right clicking the bar with the patient results and selecting Show Slice in Reporting Workbench
17. In **Reporting Workbench**, select the **Display** tab to set all display columns for the report. Search for any display information in the Available Columns pane. Select all desired columns and click the right arrow to drag to the Selected Columns pane
18. In the **General** tab, enter the desired Report Name (eg, **"Patients Requiring Chart Review to Determine ETCAMAH Eligibility"** or "**Patients w/ HR+/HER2- mBC and *ESR1*m Results Requiring Chart Review"**) and a Description. Results can be shared with selected users or pools
19. Click **Save** and **Run** to create the patient list. The list will display all patients matching the criteria

Note: The above steps do not consider the results of the *ESR1*m biomarker test as *ESR1*m test results may not be stored in discrete fields within the EHR. For the patients who are listed on the output of the report, the recommendation is a manual chart review of *ESR1*m biomarker status to determine eligibility. If, upon review, an *ESR1* mutation is detected, these patients could be considered for ETCAMAH. If, upon review, an *ESR1* mutation is not detected, these patients may be eligible for routine monitoring for *ESR1*m emergence ahead of disease progression. For organizations where *ESR1*m biomarker test results are stored as discrete fields in the EHR, proceed to the following additional steps.

Suggested Instructions to Identify Patients With HR-Positive, HER2-Negative, Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During AI and CDK4/6i Therapy, Based on an FDA-Authorized Test, or Those Eligible for *ESR1*m Testing (cont'd)

Additional Steps to Identify Patients With *ESR1*m Test With Structured Result

13. In the Search for criteria field, enter *"ESR1"* or "genomic" and select the appropriate test result (eg, *ESR1*m – genomic variant result)
    - **Depending on the build at your organization, you may also have the ability to select options related to the *ESR1*m result pertaining to Variant Classification (Likely Benign, Pathogenic, Tier 1, Tier 2, etc), Assessment (Detected, Indeterminate, Negative, Not Detected), AA Change, DNA Change**
14. Setting the logic:
    - Set the logic to include patient living status AND age AND BOTH HR-positive/HER2-negative status AND at least 1 of the locally advanced OR metastatic breast cancer diagnoses AND existence of aromatase inhibitor and CDK4/6 inhibitor therapy AND existence of the genomic variant result for *ESR1*m
15. Click the last icon with the detail table in the Visual Option section to see the query results
16. The results can be exported to Reporting Workbench by right clicking the bar with the patient results and selecting Show Slice in Reporting Workbench
17. In **Reporting Workbench**, select the **Display** tab to set all display columns for the report. Search for any display information in the Available Columns pane. Select all desired columns and click the right arrow to drag to the Selected Columns pane
18. In the **General** tab, enter the desired Report Name (eg, **"Patients With *ESR1*m Results to Consider for ETCAMAH Eligibility"** or **"Patients w/ HR+/HER2- mBC and *ESR1*m Results to Consider for ETCAMAH Eligibility"**) and a Description. Results can be shared with selected users or pools
19. Click **Save** and **Run** to create the patient list. The list will display all patients matching the criteria

Note: While the above steps do consider *ESR1*m test results stored in discrete fields, depending on workflow for incorporating external results at your organization, you may still consider a manual chart review to confirm results. The above list can be filtered to display patients with the desired *ESR1* mutation(s) to consider for ETCAMAH. When no *ESR1* mutation is detected, these patients may be eligible for routine monitoring for *ESR1*m emergence ahead of disease progression.

Updating AI and CDK4/6i Treatment Plans for Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During 1L With ETCAMAH, for Oral Use

Overview and Limitations

This document is intended to provide health systems with instructions to update treatment plans for the Epic® EHR system with the following approved indication[2]:

- In combination with a CDK4/6i (palbociclib, ribociclib, or abemaciclib), ETCAMAH is indicated for the treatment of adult patients with HR-positive, HER2-negative, locally advanced or metastatic breast cancer upon detection of *ESR1* mutation during aromatase inhibitor and CDK4/6 inhibitor therapy, based on an FDA-authorized test

This indication is approved under accelerated approval based on progression-free survival as measured from detection of *ESR1* mutation. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

This guide is for the Epic EHR system and is not appropriate for other conditions, treatments, or therapeutic areas, or for other EHR systems. This guide is not endorsed, certified, or sponsored by Epic. Epic is not affiliated with AstraZeneca products and services.

The process outlined in this document is variable, and not all steps will apply to every organization. Any steps or settings that are not part of an organization's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The organization is solely responsible for implementing, testing, monitoring, and the ongoing operation of any EHR tools.

Considerations

Treatment plans are commonly used in the management of oncology patients—your organization may refer to these as Beacon plans, treatment regimens, or protocols. After their initial release, treatment plans may benefit from clinical updates to incorporate new products or new indications. The optimization of treatment plans is a common process and provides an opportunity to incorporate treatment updates. Treatment plans are typically modified at the health system level to help reduce practice variation.

Typically, an organization will conduct a clinical review to confirm and approve the suggested optimization. Various stakeholders may participate in reviewing treatment plan optimization requests prior to implementation.

Updating AI and CDK4/6i Treatment Plans for Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During 1L With ETCAMAH, for Oral Use (cont'd)

Suggested Treatment Plan

ETCAMAH is an oral next-generation selective estrogen receptor degrader (ngSERD) and complete estrogen receptor (ER) antagonist indicated under Accelerated Approval[2]:

- In combination with a CDK4/6i (palbociclib, ribociclib, or abemaciclib) for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer upon detection of *ESR1* mutation during aromatase inhibitor and CDK4/6i therapy, based on an FDA-authorized test

Key clinical details from the ETCAMAH Prescribing Information are included below and may be incorporated as part of the treatment plan update based on steps in the instructions section that follows. The instructions are not fully inclusive of all details of the ETCAMAH Prescribing Information. The Prescribing Information in this section is only suggestive, and it is strongly recommended that clinical and operational leadership align the treatment plan contents with the expectations and goals of the organization. The organization may add or edit any details as desired to align with governing EHR policies and standards.

Please consult the most recent version of the ETCAMAH Prescribing Information for full medication details.

Updating AI and CDK4/6i Treatment Plans for Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During 1L With ETCAMAH, for Oral Use (cont'd)

Dosage and Administration[2]

Patient Selection

Select patients with HR-positive, HER2-negative locally advanced or metastatic breast cancer who have received at least 6 months of an aromatase inhibitor and CDK4/6 inhibitor therapy for treatment with ETCAMAH in combination with a CDK4/6 inhibitor based on the presence of an *ESR1* mutation in plasma specimens, using an FDA-authorized test performed every 3 months until an *ESR1* mutation has been detected *[see Indications and Usage (1) and Clinical Studies (14)]*.

Information on FDA-authorized tests for the detection of an *ESR1* mutation in breast cancer is available at: https://www.fda.gov/CompanionDiagnostics.

Recommended Cardiac Evaluation

Perform an electrocardiogram (ECG) prior to initiating ETCAMAH, then every week for the first 2 weeks of treatment, and periodically during treatment as clinically indicated *[see Warnings and Precautions (5.1)]*.

Monitor heart rate more frequently during the first 30 days of treatment with ETCAMAH in patients with bradycardia (resting heart rate less than 60 bpm) at baseline and those on concomitant medications known to lower heart rate (eg, beta-blockers) *[see Warnings and Precautions (5.2)]*.

Recommended Dosage and Administration

The recommended dosage of ETCAMAH is 75 mg orally once daily, with or without food, until disease progression or unacceptable toxicity *[see Clinical Pharmacology (12.3)]*.

Administer ETCAMAH in combination with a CDK4/6 inhibitor (abemaciclib, palbociclib, or ribociclib). Continue the CDK4/6 inhibitor at the same dosage as when the *ESR1* mutation was detected. Refer to the Prescribing Information of the CDK4/6 inhibitor for additional dosing information *[see Clinical Studies (14)]*.

Take ETCAMAH at approximately the same time each day.

Swallow tablets whole. Do not cut, crush, or chew tablets prior to swallowing. Do not take broken, cracked, or otherwise not intact tablets.

If a dose is missed within 6 hours, take the missed dose. If a dose of ETCAMAH is missed for more than 6 hours, skip the dose for the day and take the next dose at the usual time.

If a dose is vomited, do not take an additional dose and take the next dose at the usual time.

Updating AI and CDK4/6i Treatment Plans for Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During 1L With ETCAMAH, for Oral Use (cont'd)

Dosage Modifications for Adverse Reactions[2]

The recommended dosage modifications for ETCAMAH for adverse reactions are provided in Table 1.

Table 1. Recommended Dosage Modifications for ETCAMAH

Adverse Reaction	Severity*	ETCAMAH Dosage Modifications
QTc Interval Prolongation† *[see Warnings and Precautions (5.1)]*	QTc > 500 msec or QTc > 480 msec and prolongation from baseline > 60 msec	Withhold ETCAMAH. If other contributing causes are identified, then treat or correct the contributing causes. Resume ETCAMAH when QTc returns to < 480 msec. Reassess ECGs weekly for the first 2 weeks of treatment, and periodically during treatment as clinically indicated. Permanently discontinue ETCAMAH if QTc interval prolongation is either > 500 msec or > 60 msec change from baseline AND associated with any of the following: Torsades de Pointes, polymorphic ventricular tachycardia, syncope, or signs/symptoms of serious arrhythmia.
Bradycardia‡ *[see Warnings and Precautions (5.2)]*	Symptomatic, Grade 2 or above	Withhold ETCAMAH until symptoms resolve. Obtain ECG to evaluate etiology of symptomatic bradycardia. If a contributing concomitant medication is identified, modify the dosage or discontinue this medication as appropriate until bradycardia symptoms resolve and then resume ETCAMAH. Consider reassessing the heart rate after restart of ETCAMAH. Permanently discontinue ETCAMAH for persistent symptomatic bradycardia.
Visual Disturbances§ *[see Adverse Reactions (6.1)]*	Grade 2 or above/ limiting instrumental ADLs	Withhold ETCAMAH until symptoms resolve to Grade 1 or below. Refer the patient to an eye care professional for an ophthalmic examination and treatment. Reassess visual disturbances at the next visit.
Other Adverse Reactions *[see Adverse Reactions (6.1)]*	Grade 3 or higher	Withhold ETCAMAH until resolution to Grade 2 or below, then resume ETCAMAH. Permanently discontinue ETCAMAH for recurrence of Grade 3 or higher adverse reactions.

Refer to the Prescribing Information for the co-administered CDK4/6 inhibitor for dosage modification guidelines related to adverse reactions, organ impairment, and drug-drug interactions.

*Severity as defined by NCI CTCAE version 5.0.

†Heart-rate corrected QTc using Fridericia's method.

‡Bradycardia includes bradycardia and sinus bradycardia.

§Visual disturbances include: photopsia, blurred vision, visual field defect, decreased visual acuity, visual impairment, diplopia, photophobia and visual perseveration.

ADL = Activities of daily living; CTCAE = Common Terminology Criteria for Adverse Events; ECG = electrocardiogram; NCI = National Cancer Institute.

Updating AI and CDK4/6i Treatment Plans for Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During 1L With ETCAMAH, for Oral Use (cont'd)

Drug Interactions[2]

Effect of Other Drugs on ETCAMAH

Table 5 describes drug interactions where concomitant use of another drug affects ETCAMAH.

Table 5. Drug Interactions Involving ETCAMAH and Other Drug Products

Strong CYP3A Inhibitors	
Prevention or Management	• Monitor for increased adverse reactions to ETCAMAH and modify the dosage as recommended *[see Dosage and Administration (2.4)]*
Mechanism and Clinical Effect	• Camizestrant is a CYP3A substrate. Concomitant use with strong CYP3A inhibitors increases camizestrant plasma concentrations *[see Clinical Pharmacology (12.3)]*, which may increase the risk of adverse reactions related to ETCAMAH • ETCAMAH is indicated to be used in combination with CDK4/6 inhibitors, including ribociclib, which is a strong CYP3A inhibitor and can prolong the QT interval *[see Warnings and Precautions (5.1) and Drug Interactions (7.3)]*
Strong and Moderate CYP3A Inducers	
Prevention or Management	• Avoid concomitant use of strong CYP3A inducers • The co-administration of ETCAMAH and a moderate CYP3A inducer is allowed with caution • The dosage recommendations for concomitant use of moderate CYP3A inducers differ depending on the CDK4/6 inhibitor used in combination with ETCAMAH – Avoid concomitant use of moderate CYP3A inducers for patients who are receiving ETCAMAH in combination with abemaciclib or palbociclib. If concomitant use cannot be avoided, increase the ETCAMAH dosage from 75 mg once daily to 150 mg once daily for patients who are receiving ETCAMAH in combination with abemaciclib or palbociclib *[see Dosage and Administration (2.6)]*. After the moderate CYP3A inducer has been discontinued for at least 14 days, resume the ETCAMAH dosage used prior to initiation of the moderate CYP3A inducer – For patients who are receiving ETCAMAH in combination with ribociclib concomitantly with a moderate CYP3A inducer, no ETCAMAH dosage modification is recommended
Mechanism and Clinical Effect	• Camizestrant is a CYP3A substrate. Concomitant use with strong or moderate CYP3A inducers decreases camizestrant plasma concentrations *[see Clinical Pharmacology (12.3)],* which may reduce ETCAMAH effectiveness

CYP3A = cytochrome P450 family 3, subfamily A.

Updating AI and CDK4/6i Treatment Plans for Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During 1L With ETCAMAH, for Oral Use (cont'd)

Drug Interactions[2] (cont'd)

Effect of ETCAMAH on Other Drugs

Table 6 describes drug interactions where concomitant use of ETCAMAH affects another drug.

Table 6. Drug Interactions Involving ETCAMAH and Other Drug Products

CYP2C9 Substrates or CYP2C19 Substrates	
Prevention or Management	• Avoid concomitant use of ETCAMAH with CYP2C9 substrates or CYP2C19 substrates during treatment with ETCAMAH and at least 2 weeks after the last dose of ETCAMAH, unless otherwise recommended in the Prescribing Information of the CYP2C9 substrate or CYP2C19 substrate
Mechanism and Clinical Effect	• ETCAMAH is a strong CYP2C9 inhibitor and a strong CYP2C19 inhibitor • ETCAMAH is predicted to increase the exposure of both CYP2C9 substrates and CYP2C19 substrates *[see Clinical Pharmacology (12.3)]*, which may increase the risk of adverse reactions related to these substrates
Certain CYP3A Substrates	
Prevention or Management	• Refer to the Prescribing Information for CYP3A substrates where minimal increases in the concentration may lead to serious adverse reactions
Mechanism and Clinical Effect	• ETCAMAH is a CYP3A inhibitor • ETCAMAH increases exposure of CYP3A substrates *[see Clinical Pharmacology (12.3)]*, which may increase the risk of adverse reactions related to these substrates

Drugs That Prolong the QTc Interval[2]

ETCAMAH is indicated in combination with a CDK4/6 inhibitor and there is increased risk of QTc interval prolongation with ribociclib, a strong CYP3A inhibitor that can prolong the QTc interval *[see Drug Interactions (7.1)]*. Refer to the ribociclib prescribing information for dosage modifications.

Avoid concomitant use of ETCAMAH with products (other than ribociclib) known to prolong the QTc interval and/or have a known risk of Torsades de Pointes. If concomitant use with other products cannot be avoided, monitor the QTc interval more frequently *[see Warnings and Precautions (5.1)]*.

ETCAMAH in combination with a CDK4/6 inhibitor is associated with QTc interval prolongation *[see Clinical Pharmacology (12.2)]*.

Drugs That Cause Bradycardia[2]

Avoid concomitant use of ETCAMAH with other products known to cause bradycardia. Monitor for signs and symptoms of bradycardia if concomitant use cannot be avoided *[see Warnings and Precautions (5.2)]*.

ETCAMAH causes decreases in heart rate that are dose and baseline heart rate dependent *[see Clinical Pharmacology (12.2)]*.

There are no contraindications for ETCAMAH.

CYP2C9 = cytochrome P450 family 2, subfamily C, member 9; CYP2C19 = cytochrome P450 family 2, subfamily C, member 19.

Please see additional Important Safety Information on pages 32 to 34 and full Prescribing Information, including Boxed WARNING, and Patient Information for ETCAMAH.

Suggested Instructions to Update AI and CDK4/6i Treatment Plans for Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During 1L With ETCAMAH, for Oral Use

An existing treatment plan may be used as the foundation for a new one. For instance, an available clinical research treatment plan for ETCAMAH may be available to use as a foundation in certain institutions. Consider modifying an existing treatment plan that includes ETCAMAH or a CDK4/6i (palbociclib, ribociclib, or abemaciclib) as a starting template, while saving the original protocol. If an existing treatment plan is unavailable, create a new one.

The steps below detail how to create the treatment plan:

There are 3 main steps to creating a treatment plan in the Epic® EHR system:

- **Step 1: Create or update the order groups.** As part of this step, multiple order groups related to ETCAMAH may be created/updated. Order groups for ETCAMAH and patient selection may be created, as well as for any other desired order groups (eg, treatment conditions, monitoring and hold parameters, Warnings and Precautions, supportive care, genomic variant testing, schedulable orders, HCP communications, hydration, and other sections as desired). Review your organization's governing rules and principles regarding the treatment plan and adjust the optimization appropriately. The same order groups may be used in the different treatment plans
- **Step 2: Add links** for the Prescribing Information and other resources to the medication record
- **Step 3: Add the order groups** created in Step 1 to the new treatment plan

Suggested Instructions to Update AI and CDK4/6i Treatment Plans for Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During 1L With ETCAMAH, for Oral Use (cont'd)

Step 1: Create or Update the Order Groups

1. Review the **Regimen Category Order Group** to confirm that Medications, Patient Selection, Treatment Conditions, and Supportive Medications are values in the category list
2. Select the **Order Group Builder** (Admin > Beacon Admin > Order Group Builder)
3. Create the **new order groups** (see detailed examples below)

Order Group 1: ETCAMAH with a CDK4/6i (palbociclib, ribociclib, or abemaciclib) for the treatment of adult patients with HR-positive, HER2-negative locally advanced or metastatic breast cancer upon detection of *ESR1* mutation during aromatase inhibitor and CDK4/6 inhibitor therapy

1. Review the **Regimen Category Order Group** to confirm that **Medications** is a value in the category list
2. Select the **Order Group Builder** (Admin > Beacon Admin > Order Group Builder)
3. Create a **new order group** named "ETCAMAH for 1L HR-Positive, HER2-Negative Locally Advanced or Metastatic Breast Cancer With Detected *ESR1* Mutation"
4. Set the default category to **Medications**
5. Add the **details** for ETCAMAH to the order group:
   - Right click in the empty field at the bottom of the window
   - Select Add Orders > choose ETCAMAH
   - Complete the medication details for ETCAMAH. Details may include Sig (instructions), dose, route, frequency, offset time, admin over, and any free-form special admin instructions for the nurse:
     - The recommended dosage of ETCAMAH is 75 mg orally once daily, with or without food, until disease progression or unacceptable toxicity
     - Administer ETCAMAH in combination with a CDK4/6 inhibitor (abemaciclib, palbociclib, or ribociclib). Continue the CDK4/6 inhibitor at the same dosage as when the *ESR1* mutation was detected. Refer to the Prescribing Information of the CDK4/6 inhibitor for additional dosing information *[see Clinical Studies (14)]*
     - Take ETCAMAH at approximately the same time each day
     - Swallow tablets whole. Do not cut, crush, or chew tablets prior to swallowing. Do not take broken, cracked, or otherwise not intact tablets
     - If a dose is missed within 6 hours, take the missed dose. If a dose of ETCAMAH is missed for more than 6 hours, skip the dose for the day and take the next dose at the usual time
     - If a dose is vomited, do not take an additional dose and take the next dose at the usual time
6. Once all the desired information is added, release the Order Group to the production environment after completing testing

Suggested Instructions to Update AI and CDK4/6i Treatment Plans for Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During 1L With ETCAMAH, for Oral Use (cont'd)

Order Groups Specific to QTc Interval Prolongation Monitoring and Intervention While on ETCAMAH

Note: If your organization has existing oncology-specific QTc interval prolongation monitoring and intervention Order Groups, consider reviewing those order groups for inclusion in the order set if appropriate.

QTc Interval Prolongation: defined as QTc > 500 msec or QTc > 480 msec and prolongation from baseline > 60 msec

Consider including Order Groups for the following items specific to QTc interval prolongation monitoring and intervention:

1. **Regimen Category Order Group: Labs**
   - **Default Category: Labs**
   - **Orders:** Chem 10 (or equivalent) AND Calcium ionized (whole blood)
2. **Regimen Category Order Group: Monitoring and Hold Parameters** (variable depending on EHR build)
   - **Default Category: Monitoring and Hold Parameters** OR **Schedulable Orders**
   - **Orders:** ECG / EKG AND Cardiorespiratory Monitoring
   - Recommended Frequency: Before starting treatment, every week for the first 2 weeks of treatment, and periodically during treatment as clinically indicated
3. **Regimen Category Order Group: Consults**
   - **Default Category: Consult**
   - **Order: Cardiology Consult**

Suggested Instructions to Update AI and CDK4/6i Treatment Plans for Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During 1L With ETCAMAH, for Oral Use (cont'd)

Step 1: Create or Update the Order Groups (cont'd)

Additional Order Groups

Add the other desired order groups for ETCAMAH (eg, treatment conditions, monitoring and hold parameters, Warnings and Precautions, supportive care, schedulable orders, HCP communications, hydration, and other sections) as desired.

Consider the Prescribing Information below for other order groups:

- There are dosage modifications for Adverse Reactions. *(See the Dosage Modifications section starting on Page 3 or see Dose Modifications for Adverse Reactions [2.4])*. Consider adding a referral to an eye care professional
- For dosage in patients with hepatic impairment, see Section 2.5 of the Prescribing Information:

Dosage in Patients With Hepatic Impairment (2.5):

  – The recommended dosage for patients with hepatic impairment differs depending on the CDK4/6 inhibitor used in combination with ETCAMAH
  – For patients with severe (Child-Pugh C) hepatic impairment who are receiving ETCAMAH in combination with ribociclib, the recommended dosage of ETCAMAH is 75 mg once every other day
  – For patients with severe (Child-Pugh C) hepatic impairment who are receiving ETCAMAH in combination with abemaciclib or palbociclib, no dosage modification of ETCAMAH is recommended
  – Monitor patients with moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment receiving ETCAMAH in combination with any CDK4/6 inhibitor for increased adverse reactions and modify the dosage as recommended *[see Dosage and Administration (2.4)]*

- For adverse reactions, see Section 6 of the Prescribing Information

Step 2: Add Links for the Prescribing Information and Other Resources

1. Log in to the **Medication Master File (ERX)** with authorized user credentials
2. Use the search feature in the Medication Master File to search for and select ETCAMAH
3. Select the **Patient Medication References** screen and create 6 new rows:
   a. Row 1: For Display Name, enter "ETCAMAH Prescribing Information."
      In the Text field, enter "See URL for additional ETCAMAH Prescribing Information."
      In the URL field, enter this hyperlink: https://www.azpicentral.com/pi.html?product=etcamah
   b. Row 2: For Display Name, enter "Patient Information."
      In the Text field, enter "See URL for Patient Information"
      In the URL field, enter this hyperlink:
      https://www.azpicentral.com/pi.html?product=etcamah&medguide=y

Suggested Instructions to Update AI and CDK4/6i Treatment Plans for Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During 1L With ETCAMAH, for Oral Use (cont'd)

Step 2: Add Links for the Prescribing Information and Other Resources (cont'd)

c. Row 3: For Display Name, enter "Provider Support and Resources"

In the Text field, enter "See URL for Provider Support and Resources."
In the URL field, enter this hyperlink: www.ETCAMAHhcp.com/access-and-resources

d. Row 4: For Display Name, enter "Additional resources for Patients and Caregivers"

In the Text field, enter "See URL for additional resources for Patients and Caregivers"
In the URL field, enter this hyperlink: www.etcamah.com/educational-resources

e. Row 5: For Display Name, enter "Dosage and administration details for ETCAMAH"

In the Text field, enter "See URL for dosage and administration details for ETCAMAH. See the Dosage and Administration section starting on Page 2 of the Prescribing Information." In the URL field, enter this hyperlink:
https://www.azpicentral.com/pi.html?product=etcamah

f. Row 6: For Display Name, enter "Clinical Study References for ETCAMAH: Locally advanced or metastatic breast cancer upon detection of *ESR1* mutation during aromatase inhibitor and CDK4/6 inhibitor therapy"

In the Text field, enter "See Section 14 (Clinical Studies) of the ETCAMAH Prescribing Information." In the URL field, enter this hyperlink:
https://www.azpicentral.com/pi.html?product=etcamah

4. Save the medication record
5. Release the record to the production environment after completing testing

Step 3: Add the Order Groups Created in Step 1 to the New Treatment Plan and Treatment Regimen Calendar

1. Click the **Epic® logo > Admin > Beacon Admin > Protocol Builder**
2. **Search** for treatment plans using the search query and entering search terms specific to the indication. Note that an existing ETCAMAH protocol may be available to optimize. When updating existing plans for ETCAMAH, consider updating relevant synonyms to reflect the indication

   Note: The existing treatment plans will only serve as a template for the new ETCAMAH protocol. If the original plan used to create the new ETCAMAH protocol includes ETCAMAH, confirm it is retired or removed from the EHR production system according to the organization's EHR governing principles
3. Add all the newly created order groups from Step 1 (order groups with ETCAMAH and other order groups) to the treatment calendar and protocol. In the **Calendar**, update and confirm the dosing for ETCAMAH:
   - The standard recommended dosage of ETCAMAH is 75 mg orally once daily, with or without food, until disease progression or unacceptable toxicity

Suggested Instructions to Update AI and CDK4/6i Treatment Plans for Locally Advanced or Metastatic Breast Cancer With an *ESR1* Mutation During 1L With ETCAMAH, for Oral Use (cont'd)

Step 3: Add the Order Groups Created in Step 1 to the New Treatment Plan and Treatment Regimen Calendar (cont'd)

4. Update the **treatment plan name for the new treatment plans.** Suggestions are listed below or select another name to align with internal naming conventions:
   - ETCAMAH in combination with CDK4/6i (palbociclib, ribociclib, or abemaciclib) for the treatment of adult patients with HR-positive, HER2-negative, locally advanced or metastatic breast cancer upon detection of *ESR1* mutation during aromatase inhibitor and CDK4/6 inhibitor therapy, based on an FDA-authorized test
5. Update the **treatment plan description for the new treatment plans.** Suggestions are listed below or select another name to align with internal naming conventions:
   - ETCAMAH in combination with a CDK4/6i (palbociclib, ribociclib, or abemaciclib) is indicated for the treatment of adult patients with HR-positive, HER2-negative, locally advanced or metastatic breast cancer upon detection of *ESR1* mutation during aromatase inhibitor and CDK4/6 inhibitor therapy, based on an FDA-authorized test
6. Update the **Synonyms** for the treatment plan. Consider adding regimen acronyms, generic names, tumor type, location, and other values specific to the treatment plan. Consider common misspellings and other combinations, which are consistent with your institution's standards. Suggested Synonyms include:
   - ETCAMAH (camizestrant) for 1L HR-positive, HER2-negative locally advanced or metastatic with *ESR1* mutation, CDK4/6i (palbociclib, ribociclib, or abemaciclib), CDK4/6, CDK46, camizestrant, cami, camiz, palbo, abema, ribo, SERENA-6, SERENA6, ctDNA, circulating DNA, HER2 negative, ngSERD, SERD, oral SERDs, SERENA, *ESR1*m, *ESR1* mutations, *ESR1*+, *ESR1*, HER2 low, HER2 ultralow, ER-positive, PR-positive
7. Update the Clinical Study Reference for ETCAMAH (consider a link to Section 14 [Clinical Studies] of the ETCAMAH Prescribing Information)
8. Click Save
9. **Release** the treatment plan to the production environment after completing testing

   To **preference** the new ETCAMAH treatment plans, navigate to the protocol selection window and click the star icon before the name of the newly created ETCAMAH plan to add to the Preference list.

ER = estrogen receptor; PR = progesterone receptor; SERD = selective estrogen receptor degrader.

Suggested Instructions to Update Treatment Plans for Metastatic Breast Cancer That Use CDK4/6i With an AI to Include *ESR1*m Genomic Variant Testing Order Group

Step 1: Create or Update the Order Group

Search for existing treatment plans currently in use at your organization for advanced or metastatic breast cancer that include CDK4/6i (palbociclib, ribociclib, or abemaciclib) with AI treatment (exemestane, anastrozole, letrozole). Consider adding *ESR1*m genomic variant testing to these existing treatment plans:

1. Determine if your organization has an existing order group for the *ESR1*m genomic variant test (Note that many organizations have custom order groups for genomic testing). If not, continue with the below steps.
2. Review the **Regimen Category Order Group** to confirm **whichever order group your organization uses for genomic variant testing (eg, custom, Oncology, Genomic Testing, or NGS Panel)** is a value in the category list
3. Select the **Order Group Builder** (Admin > Beacon Admin > Order Group Builder)
4. Create a **new order group** named "*ESR1*m Testing"
5. Set the default category to whichever category was selected in Step 2 above.
6. Add the details for *ESR1*m testing to the order group:
   - Right click in the empty field at the bottom of the window
   - Select Add Orders > choose the *ESR1*m test utilized by the organization
   - The *ESR1*m test chosen should be blood-based (such as a circulating tumor DNA [ctDNA] blood test)

Integrating Appropriate Timing for *ESR1*m Testing Into the Calendar

7. In the **Calendar**, add the details for the appropriate timing of *ESR1*m testing to include:
   - Initial testing to occur after 6 months of CDK4/6i + AI treatment (this can be done by selecting a specific date on the calendar as the start date or entering +6M to indicate a start date of 6 months from the current date, or +180D to indicate a start date of 180 days from the current date)
   - Testing to occur every 3 months (every 90 days) OR until detection of *ESR1* mutation

While *ESR1*m testing is recommended at least every 3 months until detection of a mutation, if your organization performs routine blood work (ie, CBC, CMP) more frequently (ie, every 2 months) and chooses to include *ESR1*m ctDNA testing with that more frequent blood work, you may choose to do so at your organization's discretion. Whichever frequency is chosen, verify the *ESR1*m testing frequency is accurately reflected on the calendar

8. Once all the desired information is added, release the Order Group to the production environment after completing testing

CBC = complete blood count; CMP = comprehensive metabolic panel; NGS = next-generation sequencing.

Suggested Instructions to Update Treatment Plans for Metastatic Breast Cancer That Use CDK4/6i With an AI to Include *ESR1*m Genomic Variant Testing Order Group (cont'd)

Step 2: Add the Order Groups Created in Step 1 to the New Treatment Plan

1. Click the Epic logo > Admin > Beacon Admin > Protocol Builder
2. Search for treatment plans using the search query and entering search terms specific to the indication
3. Add the newly created order group from Step 1 to the treatment regimen
4. Consider updating the **treatment plan names to indicate *ESR1*m testing is included in the treatment plan**
5. Consider updating the **treatment plan descriptions to indicate *ESR1*m testing is included in the treatment plan**
6. Consider updating the **Synonyms** for the treatment plans to include *ESR1*m testing–relevant synonyms in addition to existing synonyms
7. Click Save
8. **Release** the treatment plan to the production environment after completing testing

   To **preference** any of the treatment plans (if not already preferenced), navigate to the protocol selection window and click the star icon before the name of the plans to add any to the Preference list.

Notes

- The customer (eg, physician, medical group, integrated delivery network) shall be solely responsible for the implementation, testing, and monitoring of the instructions to ensure proper orientation in each customer's EHR system
- Capabilities, functionality, and setup (customization) for each EHR system may vary. AstraZeneca shall not be responsible for revising the implementation instructions it provides to any customer if the customer modifies or changes its software, or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by AstraZeneca
- While AstraZeneca tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems, and AstraZeneca shall have no liability thereto
- While EHRs may assist practitioners in identifying appropriate patients for consideration of assessment, treatment, and referral, the decision and action should ultimately be decided by a practitioner in consultation with the patient, after a review of the patient's records to determine eligibility, and AstraZeneca shall have no liability thereto
- The instructions have not been designed for, and are not tools and/or solutions for, meeting Advancing Care Information and/or any other quality/accreditation requirement
- All products are trademarks of their respective holders; all rights reserved. Reference to these products is not intended to imply affiliation with or sponsorship of AstraZeneca or its affiliates

Notes (cont'd)

Appendix A:
ICD-10 Codes for Breast Cancer[1]
Additional criteria are needed to properly stage and a manual chart review may be needed to confirm presence of locally advanced disease

- C50.011 Malignant neoplasm of nipple and areola, right female breast
- C50.012 Malignant neoplasm of nipple and areola, left female breast
- C50.019 Malignant neoplasm of nipple and areola, unspecified female breast
- C50.021 Malignant neoplasm of nipple and areola, right male breast
- C50.022 Malignant neoplasm of nipple and areola, left male breast
- C50.029 Malignant neoplasm of nipple and areola, unspecified male breast
- C50.111 Malignant neoplasm of central portion of right female breast
- C50.112 Malignant neoplasm of central portion of left female breast
- C50.119 Malignant neoplasm of central portion of unspecified female breast
- C50.121 Malignant neoplasm of central portion of right male breast
- C50.122 Malignant neoplasm of central portion of left male breast
- C50.129 Malignant neoplasm of central portion of unspecified male breast
- C50.211 Malignant neoplasm of upper-inner quadrant of right female breast
- C50.212 Malignant neoplasm of upper-inner quadrant of left female breast
- C50.219 Malignant neoplasm of upper-inner quadrant of unspecified female breast
- C50.221 Malignant neoplasm of upper-inner quadrant of right male breast
- C50.222 Malignant neoplasm of upper-inner quadrant of left male breast
- C50.229 Malignant neoplasm of upper-inner quadrant of unspecified male breast
- C50.311 Malignant neoplasm of lower-inner quadrant of right female breast
- C50.312 Malignant neoplasm of lower-inner quadrant of left female breast
- C50.319 Malignant neoplasm of lower-inner quadrant of unspecified female breast
- C50.321 Malignant neoplasm of lower-inner quadrant of right male breast
- C50.322 Malignant neoplasm of lower-inner quadrant of left male breast
- C50.329 Malignant neoplasm of lower-inner quadrant of unspecified male breast

Notes (cont'd)

Appendix A:
ICD-10 Codes for Breast Cancer[1]
Additional criteria are needed to properly stage and a manual chart review may be needed to confirm presence of locally advanced disease (cont'd)

- C50.411 Malignant neoplasm of upper-outer quadrant of right female breast
- C50.412 Malignant neoplasm of upper-outer quadrant of left female breast
- C50.419 Malignant neoplasm of upper-outer quadrant of unspecified female breast
- C50.421 Malignant neoplasm of upper-outer quadrant of right male breast
- C50.422 Malignant neoplasm of upper-outer quadrant of left male breast
- C50.429 Malignant neoplasm of upper-outer quadrant of unspecified male breast
- C50.511 Malignant neoplasm of lower-outer quadrant of right female breast
- C50.512 Malignant neoplasm of lower-outer quadrant of left female breast
- C50.519 Malignant neoplasm of lower-outer quadrant of unspecified female breast
- C50.521 Malignant neoplasm of lower-outer quadrant of right male breast
- C50.522 Malignant neoplasm of lower-outer quadrant of left male breast
- C50.529 Malignant neoplasm of lower-outer quadrant of unspecified male breast
- C50.611 Malignant neoplasm of axillary tail of right female breast
- C50.612 Malignant neoplasm of axillary tail of left female breast
- C50.619 Malignant neoplasm of axillary tail of unspecified female breast
- C50.621 Malignant neoplasm of axillary tail of right male breast
- C50.622 Malignant neoplasm of axillary tail of left male breast
- C50.629 Malignant neoplasm of axillary tail of unspecified male breast
- C50.811 Malignant neoplasm of overlapping sites of right female breast
- C50.812 Malignant neoplasm of overlapping sites of left female breast
- C50.819 Malignant neoplasm of overlapping sites of unspecified female breast
- C50.821 Malignant neoplasm of overlapping sites of right male breast
- C50.822 Malignant neoplasm of overlapping sites of left male breast
- C50.829 Malignant neoplasm of overlapping sites of unspecified male breast

Notes (cont'd)

Appendix A:
ICD-10 Codes for Breast Cancer[1]
Additional criteria are needed to properly stage and a manual chart review may be needed to confirm presence of locally advanced disease (cont'd)

- C50.911 Malignant neoplasm of unspecified site of right female breast
- C50.912 Malignant neoplasm of unspecified site of left female breast
- C50.919 Malignant neoplasm of unspecified site of unspecified female breast
- C50.921 Malignant neoplasm of unspecified site of right male breast
- C50.922 Malignant neoplasm of unspecified site of left male breast
- C50.929 Malignant neoplasm of unspecified site of unspecified male breast

Appendix B:
ICD-10 Codes Indicating Metastases

- C79.51 Secondary malignant neoplasm of bone
- C79.52 Secondary malignant neoplasm of bone marrow
- C78.00 Secondary malignant neoplasm of unspecified lung
- C78.01 Secondary malignant neoplasm of right lung
- C78.02 Secondary malignant neoplasm of left lung
- C78.1 Secondary malignant neoplasm of mediastinum
- C78.2 Secondary malignant neoplasm of pleura
- C78.30 Secondary malignant neoplasm of unspecified respiratory organ
- C78.39 Secondary malignant neoplasm of other respiratory organs
- C79.31 Secondary malignant neoplasm of brain
- C79.32 Secondary malignant neoplasm of cerebral meninges
- C78.7 Secondary malignant neoplasm of liver and intrahepatic bile duct

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING ABOUT ETCAMAH® (camizestrant)

WARNING: ARRHYTHMIA RISK WITH CONCOMITANT USE OF QTc INTERVAL PROLONGING DRUGS

ETCAMAH in combination with ribociclib, a QTc interval prolonging drug and a strong CYP3A inhibitor, or in combination with other QTc interval prolonging drugs, can increase the risk of Torsades de Pointes (TdP), other ventricular arrhythmias, and sudden death.

Avoid concomitant use of ETCAMAH with products (other than ribociclib) known to prolong the QTc interval and/or have a known risk of TdP. If concomitant use with other products cannot be avoided, monitor the QTc interval more frequently.

Obtain electrocardiogram (ECG) prior to initiation and monitor heart rate (HR) and QTc interval during treatment. Assess and correct electrolyte abnormalities prior to initiation and during treatment. Withhold ETCAMAH until resolution of QTc interval prolongation and resume or permanently discontinue ETCAMAH based on severity.

WARNINGS AND PRECAUTIONS

QTc Interval Prolongation: ETCAMAH in combination with a CDK4/6 inhibitor (CDK4/6i) is associated with QTc interval prolongation. When ETCAMAH is used in combination with ribociclib, a CDK4/6i, there is potential for increased risk of TdP, other ventricular arrhythmias, and sudden death. One Grade 4 case of TdP was observed in a dose-finding trial when ETCAMAH was used with ribociclib. In SERENA-6, QTc interval prolongation occurred in 2.6% of patients treated with ETCAMAH in combination with a CDK4/6i. QTc interval prolongation led to dose interruption in 0.6% of patients. No patients in SERENA-6 discontinued ETCAMAH due to QTc interval prolongation. ETCAMAH also causes bradycardia, which increases the risk of QTc interval prolongation.

Perform an ECG prior to initiating ETCAMAH, then every week for the first 2 weeks of treatment, and periodically during treatment as clinically indicated. Obtain serum electrolytes at baseline and during treatment as clinically indicated, and correct electrolyte abnormalities. Avoid concomitant use of ETCAMAH in combination with a CDK4/6i with products that cause QTc interval prolongation, are strong CYP3A inhibitors, and/or are drugs known to lower HR.

For QTc >500 msec or QTc >480 msec and prolongation from baseline >60 msec, withhold ETCAMAH. If other contributing causes are identified, then treat or correct the contributing causes. Resume ETCAMAH when QTc returns to <480 msec. Reassess ECGs weekly for the first 2 weeks of treatment, and periodically during treatment as clinically indicated. Permanently discontinue ETCAMAH if QTc interval prolongation is either >500 msec or >60 msec change from baseline AND associated with any: TdP, polymorphic ventricular tachycardia, syncope, or signs/symptoms of serious arrhythmia.

Bradycardia: ETCAMAH causes a decrease in HR. Bradycardia increases the risk for life-threatening arrhythmias and sudden death when concomitant QTc interval prolongation is present, such as when ETCAMAH is used in combination with ribociclib, both a QTc interval prolonging product and a strong CYP3A inhibitor. In SERENA-6, bradycardia occurred in 8% of patients. The mean HR decrease from baseline was approximately 13 beats per minute (bpm) with the maximum decrease observed on day 15. Median time to onset was 17 days (range 13 to 283) after starting ETCAMAH. No patients discontinued ETCAMAH due to bradycardia. Dose interruption occurred in 3.9% of patients. The safety of ETCAMAH has not been established in patients with a baseline resting HR <55 bpm as these patients were excluded from SERENA-6. Monitor HR more frequently during the first 30 days of treatment in patients with bradycardia (HR <60 bpm) at baseline and those on concomitant medications known to lower HR (eg, beta-blockers).

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING ABOUT ETCAMAH® (camizestrant) (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Bradycardia (cont'd): For symptomatic (Grade 2 or above) bradycardia, withhold ETCAMAH until symptoms resolve. Obtain ECG to evaluate etiology. If a contributing concomitant medication is identified, modify the dosage or discontinue this medication, as appropriate, until bradycardia symptoms resolve, then resume ETCAMAH. Consider reassessing the HR after restart. Permanently discontinue for persistent symptomatic bradycardia.

Embryo-Fetal Toxicity: Based on findings in animals and its mechanism of action, ETCAMAH can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective non-hormonal contraception during treatment with ETCAMAH and for 4 weeks after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ETCAMAH and for 1 week after the last dose.

ADVERSE REACTIONS

The most common (≥20%) adverse reactions, including laboratory abnormalities, with ETCAMAH in combination with a CDK4/6i were decreased neutrophils (68%), decreased leukocytes (66%), decreased hemoglobin (47%), decreased lymphocytes (39%), decreased platelets (36%), visual disturbances (34%), and fatigue (23%).

Permanent discontinuation due to adverse reactions occurred in 1.3% of patients. Adverse reactions that resulted in permanent discontinuation of ETCAMAH included gastroesophageal reflux disease, cholestasis and hepatic cytolysis (0.6% each). Dosage interruption of ETCAMAH due to adverse reactions occurred in 22% of patients.

Visual disturbances: For visual disturbances limiting instrumental ADLs (activities of daily living) (Grade 2) or above, withhold ETCAMAH until symptoms resolve to Grade 1 or below. Refer to an eye professional for an ophthalmic examination and treatment and reassess at the next visit.

For other Grade 3 or higher adverse reactions: Withhold ETCAMAH until resolution to Grade 2 or below, then resume. Permanently discontinue for recurrence of Grade 3 or higher adverse reactions.

DRUG INTERACTIONS

- **Strong CYP3A Inhibitors:** Monitor for increased adverse reactions to ETCAMAH and modify the dosage as recommended
- **Strong and Moderate CYP3A Inducers:** Avoid the use of strong CYP3A inducers. Use caution with the co-administration of a moderate CYP3A inducer
  - Avoid concomitant use of moderate CYP3A inducers for patients who are receiving ETCAMAH in combination with abemaciclib or palbociclib. If concomitant use cannot be avoided, increase the ETCAMAH dosage from 75 mg once daily to 150 mg once daily. After the moderate CYP3A inducer has been discontinued for at least 14 days, resume the ETCAMAH dosage used prior to initiation of the moderate CYP3A inducer
  - For patients who are receiving ETCAMAH in combination with ribociclib concomitantly with a moderate CYP3A inducer, no ETCAMAH dosage modification is recommended
- **CYP2C9 and/or CYP2C19 Substrates:** Avoid concomitant use of ETCAMAH with CYP2C9 or CYP2C19 substrates during treatment with ETCAMAH and at least 2 weeks after the last dose of ETCAMAH, unless otherwise recommended in the Prescribing Information of the CYP2C9 or CYP2C19 substrate
- **Certain CYP3A Substrates:** Refer to the Prescribing Information for CYP3A substrates where minimal increases in the concentration may lead to serious adverse reactions

Please see additional Important Safety Information on pages 32 to 34 and full Prescribing Information, including Boxed WARNING, and Patient Information for ETCAMAH.

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING ABOUT ETCAMAH® (camizestrant) (cont'd)

DRUG INTERACTIONS (cont'd)

- **Drugs that Prolong the QTc Interval:** ETCAMAH is indicated in combination with a CDK4/6i and there is increased risk of QTc interval prolongation with ribociclib, a strong CYP3A inhibitor that can prolong the QTc interval. Refer to the ribociclib Prescribing Information for dosage modifications. Avoid concomitant use of ETCAMAH with products (other than ribociclib) known to prolong the QTc interval and/or have a known risk of TdP. If concomitant use with other products cannot be avoided, monitor the QTc interval more frequently. ETCAMAH in combination with a CDK4/6i is associated with QTc interval prolongation
- **Drugs that Cause Bradycardia:** Avoid concomitant use of ETCAMAH with other products known to cause bradycardia. Monitor for signs and symptoms of bradycardia if concomitant use cannot be avoided. ETCAMAH causes decreases in HR that are dose and baseline HR dependent

Refer to the Prescribing Information for the co-administered CDK4/6i for dosage modification guidelines related to adverse reactions, organ impairment, and drug-drug interactions.

SPECIAL POPULATIONS

Pregnancy: Based on findings in animals and mechanism of action, ETCAMAH can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

Lactation: Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with ETCAMAH and for 1 week after the last dose.

Females and Males of Reproductive Potential: ETCAMAH can cause fetal harm when administered to pregnant women. Verify pregnancy status of female patients of reproductive potential prior to initiating ETCAMAH. Advise female patients of reproductive potential to use effective non-hormonal contraception during treatment with ETCAMAH and for 4 weeks after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ETCAMAH and for 1 week after the last dose. Refer to the Prescribing Information of the CDK4/6i palbociclib, if used in combination with ETCAMAH, for contraception information and use for the longest recommended post-treatment duration. ETCAMAH may impair fertility in female and male patients.

Pediatric Use: Safety and effectiveness have not been established in pediatric patients.

Hepatic Impairment: In patients with severe (Child-Pugh C) hepatic impairment, when ETCAMAH is combined with ribociclib, reduce the dosing frequency to every other day.

No dosage modifications are required in other patients with hepatic impairment of any level, or when ETCAMAH is combined with abemaciclib or palbociclib, although patients with moderate or severe hepatic impairment (Child-Pugh B or C) should be monitored for increased adverse reactions and dosage modified as recommended.

Please see full Prescribing Information, including Boxed WARNING, and Patient Information for ETCAMAH.

You may report side effects related to AstraZeneca products (Opens new window).

References: 1. Centers for Medicare & Medicaid Services. ICD-10. Accessed July 17, 2026. https://www.cms.gov/medicare/coding-billing/icd-10-codes **2.** ETCAMAH® (camizestrant) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2026.

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