# Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

## Abemaciclib (Verzenio)

### Notes:

- ^Treatment duration to be limited to 24 months for patients treated with abemaciclib for hormone-positive, HER2-negative, early or nonmetastatic breast cancer
- Dose varies based on indication
  - Initial endocrine-based therapy: 150 mg twice daily in combination with aromatase inhibitor or tamoxifen
  - Progressive disease following endocrine therapy and prior chemotherapy: 200 mg twice daily
  - Progressive disease on prior endocrine therapy: 150 mg twice daily in combination with fulvestrant (and leuprolide if pre-menopausal)

<u>Initiation (new start) criteria</u>: Non-formulary **abemaciclib (Verzenio)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescribed by a hematologist or oncologist
- Age greater than or equal to 18 years
- Patient has diagnosis of hormone-positive, HER2-negative, advanced, or metastatic breast cancer and meets the following:
  - No disease progression while on palbociclib (Ibrance) OR ribociclib (Kisqali)
  - o History of Grade 3 or 4 neutropenia with palbociclib (Ibrance) 75 mg daily
  - History of Grade 3 or 4 neutropenia with ribociclib (Kisqali) 200 mg daily OR relative contraindication to ribociclib defined as any of the following:
    - Long QT syndrome
    - Baseline QTc greater than or equal to 450 ms
    - Use of drugs that are known to prolong the QT interval
    - Use of tamoxifen
    - Use of strong CYP3A4 inhibitors
    - Uncontrolled or significant cardiac disease (such as myocardial infarction or arrhythmias within the past 12 months, congestive heart failure NYHA class III-IV or with LVEF < 50%, unstable angina, or bradycardia)

#### -OR-

- Patient has diagnosis of hormone-positive, HER2-negative, early or nonmetastatic breast cancer and meets all of the following^:
  - Will be used along with endocrine therapy (tamoxifen or an aromatase inhibitor)
  - 4 or more positive axillary lymph nodes -OR-

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1 to 3 positive axillary lymph nodes - AND - one of the following: tumor size is ≥ 5 cm -OR- tumor is histologically grade 3 (G3)

<u>Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously</u>: Non-formulary abemaciclib (Verzenio) will be covered on the prescription drug benefit when the following criteria are met:

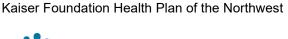
- Prescribed by a hematologist or oncologist
- Age greater than or equal to 18 years
- Diagnosis of hormone-positive, HER2-negative, advanced, or metastatic breast cancer -OR-
  - Diagnosis of hormone-positive, HER2-negative, early or non-metastatic breast cancer

<u>Criteria for new members entering Kaiser Permanente already taking the</u>
<u>medication who have not been reviewed previously</u>: Non-formulary abemaciclib
(Verzenio) will be covered on the prescription drug benefit when the following criteria are met:

- Prescribed by a hematologist or oncologist
- Age greater than or equal to 18 years
   Diagnosis of hormone-positive, HER2-negative, advanced, or metastatic breast cancer -OR-
- Diagnosis of hormone-positive, HER2-negative, early or non-metastatic breast cancer

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