VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Verzenio Prior Authorization Policy
- Verzenio® (abemaciclib tablets – Eli Lilly)

REVIEW DATE: 02/22/2023

OVERVIEW

Verzenio, a cyclin-dependent kinase (CDK) 4/6 inhibitor, is indicated for the treatment of hormone receptor-positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative **breast cancer** in adults in the following settings:[1]

- **Early breast cancer**, in combination with endocrine therapy (tamoxifen or an aromatase inhibitor [AI]) for adjuvant treatment for node-positive disease at high risk of recurrence.
- **Advanced or metastatic breast cancer:**
  - In combination with an AI as initial endocrine-based therapy.
  - In combination with fulvestrant for disease progression following endocrine therapy.
  - As monotherapy for disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on **breast cancer** (version 2.2023 – February 7, 2023) recommend Verzenio with AI (category 2A) or fulvestrant (category 1) as a first-line "Preferred Regimen" for recurrent unresectable (local or regional) or Stage IV HR+ and HER2-negative disease in postmenopausal women or premenopausal patient receiving ovarian ablation or suppression.[2,3] The guidelines state in a footnote that in phase III randomized controlled trials, Kisqali® (ribociclib tablets) + endocrine therapy has shown overall survival benefit in the first-line setting. CDK4/6 inhibitor + fulvestrant is recommended for second- and subsequent-line therapy, if CDK4/6 inhibitor was not previously used (category 1) in this setting, which is a "Preferred Regimen". The guidelines state in a footnote that in phase III randomized controlled trials, fulvestrant in combination with a CDK4/6 inhibitor has shown overall survival benefit in the second-line setting. In this setting, single-agent Verzenio is recommended as a "Useful In Certain Circumstances" therapy (for subsequent treatment) if there is progression on prior endocrine therapy and prior chemotherapy in the metastatic setting (category 2A). For men with breast cancer, the compendium recommends they be treated similarly to postmenopausal women, except that the use of an aromatase inhibitor is ineffective without concomitant suppression of testicular steroidogenesis.[3] The guidelines also recommend Verzenio for 2 years as adjuvant therapy in combination with endocrine therapy in patients with HR+, HER2-negative, high risk (i.e., ≥4 positive lymph nodes, or 1-3 positive lymph nodes with one or more of the following: grade 3 disease, tumor size ≥5 cm, or a Ki-67 score of ≥20%) disease (category 2A).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Verzenio. All approvals are provided for duration noted below. In the clinical criteria, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression; men are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Verzenio is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Breast Cancer - Early.** Approve for 2 years if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
   - **C)** Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   - **D)** Patient has node-positive disease at high risk of recurrence; AND
     Note: High risk includes patients with ≥4 positive lymph nodes, or 1-3 positive lymph nodes with one or more of the following: grade 3 disease, tumor size ≥5 cm, or a Ki-67 score of ≥20%.
   - **E)** Patient meets ONE of the following criteria (i or ii):
     - **i.** Verzenio will be used in combination with anastrozole, exemestane, or letrozole AND patient meets one of the following (a ,b, or c):
       - **a)** Patient is a postmenopausal woman*; OR
       - **b)** Patient is a pre/perimenopausual woman* and meets one of the following [(1) or (2)]:
         - **(1)** Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist; OR
           Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection).
         - **(2)** Patient has had surgical bilateral oophorectomy or ovarian irradiation; OR
       - **c)** Patient is a man* and patient is receiving a gonadotropin-releasing hormone (GnRH) analog; OR
         Note: Examples of a GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet).
     - **ii.** Verzenio will be used in combination with tamoxifen AND patient meets one of the following (a or b):
       - **a)** Patient is a postmenopausal woman* or man*; OR
       - **b)** Patient is a pre/perimenopausual woman* and meets one of the following [(1) or (2)]:
         - **(1)** Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist; OR
           Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection).
         - **(2)** Patient has had surgical bilateral oophorectomy or ovarian irradiation.

   ***** Refer to the Policy Statement.

2. **Breast Cancer – Recurrent or Metastatic in Women*.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic breast cancer; AND

C) Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
D) Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
E) Patient meets ONE of the following criteria (i or ii):
  i. Patient is postmenopausal OR
  ii. Patient is pre/perimenopausal and meets one of the following (a or b):
    a) Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist; OR
    Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant).
    b) Patient has had surgical bilateral oophorectomy or ovarian irradiation; AND
F) Patient meets ONE of the following criteria (i, ii, or iii):
  i. Verzenio will be used in combination with anastrozole, exemestane, or letrozole; OR
  ii. Verzenio will be used in combination with fulvestrant; OR
  iii. Patient meets the following conditions (a, b, and c):
    a) Verzenio will be used as monotherapy; AND
    b) Patient's breast cancer has progressed on at least one prior endocrine therapy; AND
    Note: Examples of prior endocrine therapy include anastrozole, exemestane, letrozole, tamoxifen, toremifene, exemestane plus everolimus, fulvestrant, everolimus plus fulvestrant or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol.
    c) Patient has tried chemotherapy for metastatic breast cancer.

***** Refer to the Policy Statement.

3. Breast Cancer - Recurrent or Metastatic in Men*. Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
A) Patient is ≥ 18 years of age; AND
B) Patient has recurrent or metastatic breast cancer; AND
C) Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}]disease; AND
D) Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
E) Patient meets ONE of the following criteria (i, ii, or iii):
  i. Patient meets BOTH of the following conditions (a and b):
    a) Patient is receiving a gonadotropin-releasing hormone (GnRH) analog; AND
    Note: Examples of a GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet).
    b) Verzenio will be used in combination with anastrozole, exemestane, or letrozole; OR
  ii. Verzenio will be used in combination with fulvestrant; OR
  iii. Patient meets the following conditions (a, b, and c):
    a) Verzenio will be used as monotherapy; AND
    b) Patient's breast cancer has progressed on at least one prior endocrine therapy; AND
    Note: Examples are anastrozole, exemestane, letrozole, tamoxifen, toremifene, exemestane plus everolimus, fulvestrant, everolimus plus fulvestrant or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol.
    c) Patient has tried chemotherapy for metastatic breast cancer**.**

***** Refer to the Policy Statement.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Verzenio is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Verzenio® tablets [prescribing information]. Indianapolis, IN: Eli Lilly; March 2023.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2023 – February 7, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 10, 2023.
3. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 10, 2023. Search terms: abemaciclib.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Breast Cancer – Early**: The criteria requirement "Patient has a Ki-67 score of ≥20% as determined by an FDA-approved test" was removed as criteria requirement and moved into a Note that states, "High risk includes patients with ≥4 positive lymph nodes, or 1-3 positive lymph nodes with one or more of the following: Grade 3 disease, tumor size ≥5 cm, or a Ki-67 score of ≥20%." **Breast Cancer- Recurrent or Metastatic in Women:** The condition of approval was reworded. Previously it was Breast Cancer- Advanced or Metastatic in Women. Criteria was added to ask if the patient has recurrent or metastatic disease. **Breast Cancer – Recurrent or Metastatic in Men**: The condition of approval was reworded. Previously, it was Breast Cancer – Advanced or Metastatic in Men. Criteria was added to ask if the patient has recurrent or metastatic disease.	01/26/2022
Selected Revision	**Breast Cancer – Recurrent or Metastatic in Women:** The duration of approval was changed from 3 years to 1 year. **Breast Cancer - Recurrent or Metastatic in Men:** The duration of approval was changed from 3 years to 1 year.	06/22/2022
Annual Revision	No criteria changes.	02/22/2023
Update	**03/03/2023:** The overview section was updated due to change in labeling. The following was removed from the indication of early breast cancer "Ki-67 score ≥ 20%, as determined by an FDA approved test." The following was removed from the indication of advanced and metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy, "treatment of postmenopausal women and men."	--

GnRH – Gonadotropin-releasing hormone.