VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 02/24/2021; selected revision 10/27/2021

OVERVIEW

Verzenio, a cyclin-dependent kinase (CDK) 4/6 inhibitor, is indicated in 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) for adjuvant treatment for node-positive disease at high risk of recurrence and a Ki-67 score ≥ 20%, as determined by an FDA approved test.
- **Advanced or metastatic breast cancer:**
  - In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women and men.
  - 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 8.2021 – September 13, 2021) recommend any of the CDK4/6 inhibitors in combination with an aromatase inhibitor or fulvestrant as a first-line preferred treatment option 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 (category 1).[2,3] 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. However, the guidelines also state in a footnote that if there is disease progression on CDK4/6 inhibitor therapy, there are limited data to support an additional line of therapy with another CDK4/6-containing regimen.[2,4] 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]

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 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 meets the following criteria (i and ii):
     - **i.** Patient has node-positive disease at high risk of recurrence; AND
     - **ii.** Patient has at Ki-67 score ≥ 20% as determined by an FDA approved test; AND
   - **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 Lupron (leuprolide), Trelstar (triptorelin), Zoladex (goserelin).
         - **(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 Lupron (leuprolide), Trelstar (triptorelin), Zoladex (goserelin), Firmagon (degarelix), Orgovyx (relugolix).
     - **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 Lupron (leuprolide), Trelstar (triptorelin), Zoladex (goserelin).
         - **(2)** Patient has had surgical bilateral oophorectomy or ovarian irradiation.

     ***** Refer to the Policy Statement.

2. **Breast Cancer - Advanced or Metastatic in Women***. Approve for 3 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 meets ONE of the following criteria (i or ii):
     - **i.** Patient is a postmenopausal woman*; OR
     - **ii.** Patient is a pre/perimenopausal woman* 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 Lupron (leuprolide), Trelstar (triptorelin), Zoladex (goserelin).
b) Patient has had surgical bilateral oophorectomy or ovarian irradiation; AND

E) 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, Fareston (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 - Advanced or Metastatic in Men*. Approve for 3 years if the patient meets the following criteria (A, B, C and D):
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 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 Lupron (leuprolide), Trelstar (triptorelin), Zoladex (goserelin), Firmagon (degarelix), Orgovyx (relugolix).
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, Fareston (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; October 2021.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 8.2021 – September 13, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on October 22, 2021.
3. The NCCN Drugs & Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on February 21, 2021. Search terms: abemaciclib.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Limited data are available that Verzenio can be used after the patient has progressed on Ibrance or Kisqali. Due to this, the criteria "The patient has not had disease progression while on Verzenio, Ibrance, or Kisqali" has been modified to state "The patient has not had disease progression while on Verzenio."	04/15/2020
Early Annual Revision	**All Breast Cancer Indications:** Deleted criteria requiring no disease progression on Verzenio, based on guidelines and available data. **Breast Cancer in Pre/Perimenopausal Women:** Examples of GnRH agonists are moved from criteria to Note. **Breast Cancer in Men:** GnRH "agonist" is changed to "analog". Also, the list of examples of GnRH analog agents are moved from criteria to Note. Firmagon (degarelix) and Orgovyx (relugolix) were added to example list.	02/24/2021
Selected Revision	**Breast Cancer – Early:** This condition of approval was added based on a new FDA labeled indication. **Breast Cancer – Advanced or Metastatic in Women:** The wording "advanced or metastatic" was moved from the criteria and into the condition for approval. The word "postmenopausal" was moved from the condition of approval and added into the criteria. Also, criteria for pre/perimenopausal women was added: patient is receiving ovarian suppression/ablation with a GnRH agonist OR patient has had surgical bilateral oophorectomy or ovarian irradiation; and a note with examples of GnRH agonists were added. A requirement was added that the patient is ≥ 18 years of age. **Breast Cancer in Pre/Perimenopausal Women:** This condition of approval was removed and rolled into Breast Cancer – Advanced or Metastatic in Women. **Breast Cancer - Advanced or Metastatic in Men:** This condition was moved from Other Uses with Supportive Evidence and into the FDA approved uses section. The wording "advanced or metastatic" was moved from the criteria and into the condition for approval. A requirement was added that the patient is ≥ 18 years of age.	10/27/2021

GnRH – Gonadotropin- releasing hormone.