PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 01/26/2022; selected revision 06/22/2022

OVERVIEW

Verzenio, a cyclin-dependent kinase (CDK) 4/6 inhibitor, is indicated for the treatment of adults with hormone receptor-positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative **breast cancer** 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 2.2022 – December 20, 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] The guidelines state that in phase 3 randomized controlled trials, Kisqali + 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. 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] The guidelines state that in phase 3 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 for subsequent treatment if progression on prior endocrine therapy and prior chemotherapy in the metastatic setting (useful in certain circumstances) [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 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; October 2021.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2022–December 20, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 19, 2022.
3. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 19, 2022. Search terms: abemaciclib.

GnRH – Gonadotropin- releasing hormone.