

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Verzenio Prior Authorization Policy

- Verzenio® (abemaciclib tablets – Eli Lilly)

REVIEW DATE: 02/21/2024

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

Verzenio is discussed in in guidelines from National Comprehensive Cancer Network (NCCN):

- **Breast cancer** (version 1.2024 – January 25, 2024) 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 either grade 3 disease or tumor size ≥5 cm, (category 1).
- **Endometrial Cancer:** NCCN uterine neoplasms guidelines (version 1.2024 – September 20, 2023) recommend Verzenio in combination with letrozole for recurrent or metastatic endometrial carcinoma for estrogen receptor (ER)-positive tumors (category 2A).⁵

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

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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 (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 grade 3 disease or tumor size ≥ 5 cm
 - E)** Patient meets **ONE** of the following (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/perimenopausal 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/perimenopausal 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 (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 (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 (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 (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 (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.

Other Uses with Supportive Evidence

- 4. **Endometrial Cancer.** Approve for 1 year if the patient meets the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has recurrent or metastatic disease; AND
 - C) Patient has estrogen receptor (ER)-positive tumors; AND
 - D) Patient will be using in combination with letrozole.

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 1.2024 – January 25, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 19, 2024.
- 3. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 19, 2024. Search terms: abemaciclib.
- 4. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2024 – September 20, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 19, 2024.