PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 02/26/2025

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

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 the National Comprehensive Cancer Network (NCCN):

- **Breast Cancer:** NCCN guidelines (version 1.2025 – January 31, 2025) 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.[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) as 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). The guidelines 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). Verzenio is also recommended for treatment of recurrent, unresectable (local or regional) or stage IV HR+, HER-2 positive disease as fourth-line therapy and beyond in combination with fulvestrant and trastuzumab (category 2B). The recommendations above are for postmenopausal women or premenopausal patient receiving ovarian ablation or suppression. 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]

- **Endometrial Cancer**: NCCN uterine neoplasms guidelines (version 2.2025 – January 31, 2025) 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 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.

- **Verzenio® (abemaciclib tablets (Eli Lilly)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Breast Cancer - Early.** Approve for 2 years (total) if the patient meets ALL of the following (A, B, C, D, and E):
   Note: This indication applies to both women* and men*.
   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/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 ALL of 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 meets ONE of the following (i or ii):
      i. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND meets ONE of the following:
         a) Verzenio will be used in combination with anastrozole, exemestane, or letrozole; OR
         b) Verzenio will be used in combination with fulvestrant; OR
         c) Patient meets ALL of the following [(1), (2) and (3)]:
            (1) Verzenio will be used as monotherapy; AND
            (2) 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.
            (3) Patient has tried chemotherapy for metastatic breast cancer; OR
      ii. Patient has human epidermal growth factor receptor 2 (HER2)-positive breast cancer and meets BOTH of the following (a and b):
         a) Patient has received at least three prior anti-HER2-based regimen in the metastatic setting; AND
         Note: Examples of anti-HER2-based regimens include Perjeta (pertuzumab intravenous infusion) + trastuzumab + docetaxel, Perjeta + trastuzumab + paclitaxel; Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion); Tukysa (tucatinib tablets) + trastuzumab + capecitabine; Kadcyla (ado-trastuzumab emtansine intravenous infusion).
         b) Verzenio will be used in combination with fulvestrant and trastuzumab; 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

   ***** 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, and D):
   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 meets ONE of the following (i or ii):
      i. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer and patient meets ONE of the following (a, b, or c):
         a) Patient meets BOTH of the following conditions [(1) and (2)]:
            (1) 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).
            (2) Verzenio will be used in combination with anastrozole, exemestane, or letrozole; OR
         b) Verzenio will be used in combination with fulvestrant; OR
         c) Patient meets ALL of the following [(1), (2) and (3)]:
            (1) Verzenio will be used as monotherapy; AND
            (2) 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.
            (3) Patient has tried chemotherapy for metastatic breast cancer; OR
      ii. Patient has human epidermal growth factor receptor 2 (HER2)-positive breast cancer and meets BOTH of the following (a and b):
         a) Patient has received at least three prior anti-HER2-based regimen in the metastatic setting; AND
         Note: Examples of anti-HER2-based regimens include Perjeta (pertuzumab intravenous infusion) + trastuzumab + docetaxel, Perjeta + trastuzumab + paclitaxel; Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion); Tukysa (tucatinib tablets) + trastuzumab + capecitabine; Kadcyla (ado-trastuzumab emtansine intravenous infusion).
         b) Verzenio will be used in combination with fulvestrant and trastuzumab.

   ***** Refer to the Policy Statement.

Other Uses with Supportive Evidence

4. **Endometrial Cancer.** Approve for 1 year if the patient meets ALL of 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 COVERED

- **Verzenio® (abemaciclib tablets (Eli Lilly)**

is(are) considered experimental, investigational or unproven for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Verzenio® tablets [prescribing information]. Indianapolis, IN: Eli Lilly; November 2024.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – January 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 24, 2025.
3. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 24, 2025. Search terms: abemaciclib.
4. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2025 – January 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 24, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
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."	--
Annual Revision	**Endometrial Cancer:** Condition of approval and criteria were added to "Other Uses with Supportive Evidence" section.	02/21/2024
Annual Revision	**Breast Cancer – Early:** The duration of approval from 2 years to 2 year (total). A note was added which states that this indication applies to both women and men. **Breast Cancer – Recurrent or Metastatic in Women:** The following option for approval was added, "patient has human epidermal growth factor receptor 2 (HER2)-positive breast cancer and patient has received at least three prior anti-HER2-based regimen in the metastatic setting; and Verzenio will be used in combination with fulvestrant and trastuzumab." **Breast Cancer – Recurrent or Metastatic in Men:** The following option for approval was added, "patient has human epidermal growth factor receptor 2 (HER2)-positive breast cancer and patient has received at least three prior anti-HER2-based regimen in the metastatic setting; and Verzenio will be used in combination with fulvestrant and trastuzumab."	02/26/2025