PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – Cyclin-Dependent Kinase 4 and 6 Inhibitor) – Verzenio Prior Authorization Policy
- Verzenio® (abemaciclib tablets – Eli Lilly)

REVIEW DATE: 02/18/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

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 1.2026 – January 16, 2026) have the following recommendations for patients with recurrent unresectable (local or regional) or Stage IV HR+ and HER2-negative disease as "Preferred Regimens": Verzenio + AI (category 2A) or fulvestrant (category 1) as a first-line therapy; Verzenio + fulvestrant as second- and subsequent-line therapy, if CDK4/6 inhibitor was not previously used (category 1). In this setting, the following recommendations are listed as "Useful in Certain Circumstances": Verzenio + Inluriyo™ (imlunestrant tablets) as second or subsequent-line therapy (category 2A) and single-agent Verzenio as 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 (either tamoxifen or an aromatase inhibitor) 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 2.2026 – November 14, 2025) recommend Verzenio in combination with letrozole for estrogen receptor (ER)-positive tumors as primary treatment for disease that is not suitable for surgery (category 2A/2B) or for recurrent or metastatic disease as "Useful in Certain Circumstances" (category 2A).[5]
- **Liposarcoma:** NCCN guidelines on soft tissue sarcoma (version 1.2026 – January 16, 2026) recommend Verzenio as single-agent for the treatment of dedifferentiated liposarcoma with or without concurrent well-differentiated liposarcoma or as "Useful in Certain Circumstances" (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.

- **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, b, c, or d):
       - **a)** Verzenio will be used in combination with anastrozole, exemestane, or letrozole; OR
       - **b)** Verzenio will be used in combination with fulvestrant; OR
       - **c)** Verzenio will be used in combination with Inluriyo (imlunestrant tablets); OR
       - **d)** 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, c or d):
         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) Verzenio will be used in combination with Inluriyo (imlunestrant tablets); OR
         d) 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 estrogen receptor (ER)-positive tumors; AND
   C) Patient meets ONE of the following (i or ii):
      i. According to the prescriber, the patient is not a candidate for surgery; OR
      ii. Patient has recurrent or metastatic disease; AND
   D) The medication will be used in combination with letrozole.

5. **Liposarcoma**. Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has dedifferentiated liposarcoma.

CONDITIONS NOT COVERED

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

is(are) considered not medically necessary 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; February 2025.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 1.2026 – January 16, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 16, 2026.
3. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 16, 2026. Search terms: abemaciclib.
4. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2026 – November 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 16, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
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.	02/26/2025

	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."	
Update	04/08/2025: The policy name was changed from "Oncology – Verzenio PA Policy" to "Oncology (Oral - Cyclin-Dependent Kinase 4 and 6 Inhibitor) – Verzenio PA Policy".	N/A
Annual Revision	**Breast Cancer - Recurrent or Metastatic in Women:** An option for approval was added for a patient with HER2-negative breast cancer when Verzenio is used in combination with Inluriyo (imlunestrant tablets). **Breast Cancer - Recurrent or Metastatic in Men:** An option for approval was added for a patient with HER2-negative breast cancer when Verzenio is used in combination with Inluriyo (imlunestrant tablets). **Endometrial Cancer:** An option for approval was added when according to the prescriber, the patient is not a candidate for surgery. **Liposarcoma**: Condition of approval and criteria were added to Other Uses with Supportive Evidence.	02/18/2026