UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1233-10
Program	Prior Authorization/Notification
Medication	Verzenio® (abemaciclib)
P&T Approval Date	11/2017, 5/2018, 5/2019, 5/2020, 5/2021, 1/2022, 1/2023, 5/2023, 5/2024, 5/2025
Effective Date	8/1/2025

1. Background:

Verzenio (abemaciclib) is a kinase inhibitor indicated in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence; in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer; in combination with fulvestrant for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy; and as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

The National Comprehensive Cancer Network (NCCN) recommends the use of Verzenio similarly for men and premenopausal women treated with ovarian ablation/suppression with recurrent or metastatic HR-positive, HER2-negative breast cancer disease, in combination with an aromatase inhibitor or Faslodex (fulvestrant). The use of an aromatase inhibitor in men with breast cancer is ineffective without concomitant suppression of testicular steroidogenesis. The NCCN recommends the use of Verzenio for 2 years as adjuvant therapy in combination with endocrine therapy in patients with HR-positive, 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) disease. The NCCN also recommends Verzenio for estrogen receptor (ER)-positive recurrent or metastatic endometrial carcinoma in combination with letrozole.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Verzenio** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Breast Cancer</u>

1. **<u>Initial Authorization</u>**

   a. **Verzenio** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of breast cancer

      -AND-

      (2) Disease is hormone-receptor (HR)-positive

      -AND-

      (3) Disease is human epidermal growth factor receptor 2 (HER2)-negative

      -AND-

      (4) **<u>One</u>** of the following:

         (a) **<u>Both</u>** of the following:

            i. Disease is advanced, recurrent, or metastatic

            -AND-

            ii. **<u>One</u>** of the following:

               - Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) or Faslodex (fulvestrant)

               -OR-

               - **<u>All</u>** of the following:
                  - Used as monotherapy
                  - Patient has disease progression following endocrine therapy
                  - Patient has already received at least one prior chemotherapy regimen

               -OR-

(b) **All** of the following:

i. Disease is early breast cancer at high risk of recurrence defined by **one** of the following (confirmed preoperatively and/or at surgery):

- Greater than or equal to 4 positive lymph nodes

-OR-

- **Both** of the following:
  - 1-3 positive lymph nodes
  - Grade 3 disease or tumor size ≥ 5 cm

-AND-

ii. Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) or tamoxifen

-AND-

iii. Use has not exceeded two years in duration

Authorization will be issued for 12 months

2. **Reauthorization**

a. **Verzenio** will be approved based on **one** of the following criteria:

(1) **Both** of the following:

(a) Diagnosis of advanced, recurrent, or metastatic breast cancer

-AND-

(b) Patient does not show evidence of progressive disease while on Verzenio therapy

-OR-

(2) **All** of the following:

(a) Diagnosis of early breast cancer at high risk of recurrence

-AND-

(b) Patient does not show evidence of progressive disease while on Verzenio therapy

-AND-

(c) Use has not exceeded two years in duration

Authorization will be issued for 12 months.

C. Endometrial Carcinoma

1. **Initial Authorization**

a. **Verzenio** will be approved based on **all** of the following criteria:

(1) Diagnosis of recurrent or metastatic endometrial cancer

-AND-

(2) Tumor is estrogen receptor (ER)-positive

-AND-

(3) Used in combination with letrozole

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Verzenio** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Verzenio therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Verzenio [package insert]. Indianapolis, IN: Lilly USA, LLC; February 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 10, 2025.

Program	Prior Authorization/Notification – Verzenio (abemaciclib)
Change Control	
11/2017	New program.
5/2018	Updated background and criteria to include new indication for initial endocrine-based therapy in combination with an aromatase inhibitor. Updated references.
5/2019	Annual review. Updated coverage criteria to allow diagnosis of recurrent breast cancer. Removed disease progression following endocrine therapy for concomitant use of Faslodex per NCCN. Updated background and reference.
5/2020	Annual review. Updated references and background.
5/2021	Annual review. No changes.
1/2022	Updated background and coverage criteria to include new indication for early breast cancer. Updated references.
1/2023	Annual review with no changes to coverage criteria. Added state mandate footnote and updated references.
5/2023	Removed Ki-67 score requirement for patient selection per updated prescribing information. Updated background and references.
5/2024	Annual review. Updated background and added clinical criteria for endometrial carcinoma per NCCN. Updated references.
5/2025	Annual review. Updated criteria for breast cancer per NCCN recommendations. Updated references.