



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2021 P 1233-5
Program	Prior Authorization/Notification
Medication	Verzenio <sup>®</sup> (abemaciclib)
P&T Approval Date	11/2017, 5/2018, 5/2019, 5/2020, 5/2021
Effective Date	8/1/2021; Oxford only: 8/1/2021

**1. Background:**

Verzenio<sup>®</sup> (abemaciclib) is a kinase inhibitor is indicted in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer; in combination with Faslodex<sup>®</sup> (fulvestrant) for the treatment of women 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. The use of an aromatase inhibitor in men with breast cancer is ineffective without concomitant suppression of testicular steroidogenesis.

**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. Patients less than 19 years of age

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. Breast Cancer

#### 1. Initial Authorization

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

- (1) Diagnosis of advanced, recurrent, or metastatic breast cancer

-AND-

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

-AND-

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

-AND-

- (4) **One** of the following:

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

-OR-

- (c) **All** of the following:

- i. Used as monotherapy
- ii. Patient has disease progression following endocrine therapy
- iii. Patient has already received at least one prior chemotherapy regimen

**Authorization will be issued for 12 months.**

#### 2. Reauthorization

<p>a. <b>Verzenio</b> will be approved based on the following criterion:</p> <p>(1) Patient does not show evidence of progressive disease while on Verzenio therapy</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p> <p><b>C. <u>NCCN Recommended Regimens</u></b></p> <p>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</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p>
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- 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; March 2020.
  2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [http://www.nccn.org/professionals/drug\\_compendium/content/contents.asp](http://www.nccn.org/professionals/drug_compendium/content/contents.asp). Accessed April 1, 2021.

Program	Prior Authorization/Notification – Verzenio (abemaciclib)
<b>Change Control</b>	
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.