UnitedHealthcare Community Plan

# Clinical Pharmacy Program Guidelines for Verzenio

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| Program | Prior Authorization |
| Medication | Verzenio™ (abemaciclib) |
| Markets in Scope | Arizona, California, Florida- CHIP, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Ohio, Pennsylvania, Rhode Island |
| Issue Date | 11/2017 |
| Pharmacy and Therapeutics Approval Date | 5/2019 |
| Effective Date | 7/2019 |

## 1. Background:

Verzenio™ (abemaciclib) is a kinase inhibitor indicated 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® (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 Verzenio similarly for men and premenopausal women treated with ovarian ablation/suppression with recurrent or metastatic HR-positive, HER2-negative breast cancer, 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.

## 2. Coverage Criteria:

**A. <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 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 Faslodex (fulvestrant)

**-OR-**

(b) **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

**-OR-**

(c) Used in combination with an aromatase inhibitor [e.g., Femara (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.**

**B. NCCN Recommended Regimens**

**1. Initial Authorization**

a. **Verzenio** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

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

**2. Reauthorization**

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

(1) Documentation of positive clinical response to Verzenio therapy

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

**3. References:**

1. Verzenio [package insert]. Indianapolis, IN: Lilly USA, LLC; February 2018.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). February 22, 2019.

| Program | Prior Authorization – Verzenio (abemaciclib) |
|---|---|
| **Change Control** | |
| 11/2017 | New program. |
| 4/2018 | Added criteria for additional indication. Added NCCN Recommended Regimen review criteria. Updated background and references. |
| 5/2019 | 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 references. |