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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	October 12, 2017
Subject:	Verzenio	**Page:**	1 of 6

Last Review Date: March 8, 2024

Verzenio

Description

Verzenio (abemaciclib)

Background
Verzenio (abemaciclib) is a kinase inhibitor that works by blocking certain molecules (known as cyclin-dependent kinases 4 and 6), involved in promoting the growth of cancer cells. Verzenio provides a targeted treatment option for certain patients with early breast cancer or with advanced or metastatic breast cancer (1).

Regulatory Status
FDA-approved indications: Verzenio is a kinase inhibitor indicated: (1)

1. 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 receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence.
2. In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.
3. In combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.
4. 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.

Increases in serum transaminase levels have been seen with the use of Verzenio. Perform LFTs before initiating therapy with Verzenio. Monitor LFTs every 2 weeks for first 2 months, monthly for the next 2 months. Based on severity of transaminase elevation, Verzenio may require dose interruption, reduction, or discontinuation (1).

Neutropenia was highly reported with the use of Verzenio. Perform Complete Blood Count (CBC) prior to initiating therapy with Verzenio. Monitor CBC every 2 weeks for first 2 months, monthly for the next 2 months, and as clinically indicated (1).

Diarrhea occurred in patients receiving Verzenio. Instruct patients at the first sign of loose stools to initiate antidiarrheal therapy, increase oral fluids, and notify their healthcare provider (1).

For early breast cancer, Verzenio should be continued until completion of 2 years of treatment or until disease recurrence, or unacceptable toxicity. For advanced or metastatic breast cancer, Verzenio should be continued until disease progression or unacceptable toxicity (1).

The safety and effectiveness of Verzenio have not been established in pediatric patients (1).

Related policies
Ibrance, Kisqali

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Verzenio may be considered **medically necessary** if the conditions indicated below are met.

Verzenio may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Early breast cancer
    a. HR-positive, HER2-negative, node-positive

b. Used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor)

2. Advanced or metastatic breast cancer
   a. HR-positive, HER2-negative
   b. Patient has **ONE** of the following:
      i. Used in combination with an aromatase inhibitor as initial endocrine-based therapy
      ii. Used in combination with fulvestrant for the treatment of patients with disease progression following endocrine therapy
      iii. Used as monotherapy for the treatment of patients with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting

AND the following for **ALL** diagnoses:

a. Prescriber agrees to monitor liver function tests (LFTs), and complete blood count (CBCs) prior to initiation of treatment and each month as clinically indicated

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Early breast cancer
   a. Used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor)
2. Advanced or metastatic breast cancer **AND ONE** of the following:
   a. Used in combination with an aromatase inhibitor
   b. Used in combination with fulvestrant
   c. Used as monotherapy

AND ALL of the following for **ALL** diagnoses:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor liver function tests (LFTs), and complete blood count (CBCs) each month as clinically indicated

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Quantity

Monotherapy:

Strength	Quantity
50 mg	168 tablets per 84 days
100 mg	168 tablets per 84 days
150 mg	168 tablets per 84 days
200 mg	168 tablets per 84 days

Monotherapy: Any combination up to 400mg/day

In Combination with Fulvestrant, Tamoxifen, or an aromatase inhibitor:

Strength	Quantity
50 mg	168 tablets per 84 days
100 mg	168 tablets per 84 days
150 mg	168 tablets per 84 days
200 mg	**Not applicable**

Combination Therapy: Any combination up to 300mg/day

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity

Monotherapy:

Strength	Quantity
50 mg	168 tablets per 84 days
100 mg	168 tablets per 84 days
150 mg	168 tablets per 84 days
200 mg	168 tablets per 84 days

Monotherapy: Any combination up to 400mg/day

In Combination with Fulvestrant, Tamoxifen, or an aromatase inhibitor

Strength	Quantity
50 mg	168 tablets per 84 days
100 mg	168 tablets per 84 days
150 mg	168 tablets per 84 days
200 mg	**Not applicable**

Combination therapy: Any combination up to 300mg/day

*Early breast cancer: One renewal **ONLY**

Duration 12 months

Rationale

Summary

Verzenio (abemaciclib) is a kinase inhibitor that works by blocking certain molecules (known as cyclin-dependent kinases 4 and 6), involved in promoting the growth of cancer cells. Verzenio provides a targeted treatment option for certain patients with early breast cancer or with advanced or metastatic breast cancer. The safety and effectiveness of Verzenio have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Verzenio while maintaining optimal therapeutic outcomes.

References

1. Verzenio [package insert]. Indianapolis, IN; Eli Lilly and Company; January 2024.
2. NCCN Drugs & Biologics Compendium® Abemaciclib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 11, 2024.

Policy History

Date	Action
October 2017	New Addition to PA
December 2017	Annual review
April 2018	Addition of the indication “Used in combination with an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women” for the treatment of breast cancer
June 2018	Annual review
June 2019	Annual review and reference update
December 2019	Annual review and reference update

June 2020	Annual review and reference update
October 2021	Addition of indication: early breast cancer. Revised renewal requirements to remove prior treatment status that is already confirmed in initiation. Removed “OR” from the quantity table limit to allow dose modification without the need for a new PA.
December 2021	Annual review
September 2022	Annual review and reference update
April 2023	Per PI update, removed Ki-67 score requirement for early breast cancer, included all adult patients for advanced or metastatic breast cancer
June 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.