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| <b>Section:</b>    | Prescription Drugs    | <b>Effective Date:</b>       | July 1, 2026     |
| <b>Subsection:</b> | Antineoplastic Agents | <b>Original Policy Date:</b> | October 12, 2017 |
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**Last Review Date:** June 11, 2026

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## Verzenio

### Description

#### Verzenio (abemaciclib)

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#### 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.

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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, and as clinically indicated. 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).

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#### 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

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- 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, every 2 weeks during the first 2 months of treatment, and then monthly as clinically indicated

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## 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) monthly as clinically indicated

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### Policy Guidelines

#### Pre – PA Allowance

None

#### Prior - Approval Limits

##### Quantity

###### Monotherapy:

| Strength | Quantity       |
|----------|----------------|
| 50 mg    | 400 mg per day |
| 100 mg   |                |
| 150 mg   |                |
| 200 mg   |                |

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

| Strength | Quantity       |
|----------|----------------|
| 50 mg    | 300 mg per day |
| 100 mg   |                |
| 150 mg   |                |
| 200 mg   | Not applicable |

**Duration** 12 months

#### Prior – Approval *Renewal* Limits

##### Quantity

###### Monotherapy:

| Strength | Quantity       |
|----------|----------------|
| 50 mg    | 400 mg per day |
| 100 mg   |                |
| 150 mg   |                |
| 200 mg   |                |

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

| Strength | Quantity       |
|----------|----------------|
| 50 mg    | 300 mg per day |
| 100 mg   |                |

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|        |                       |
|--------|-----------------------|
| 150 mg |                       |
| 200 mg | <b>Not applicable</b> |

\*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; February 2025.
2. NCCN Drugs & Biologics Compendium® Abemaciclib 2026. National Comprehensive Cancer Network, Inc. Accessed on April 16, 2026.

## 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. |

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|----------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                                                                           |
| June 2024      | Annual review and reference update                                                                                                           |
| March 2025     | Annual review and reference update                                                                                                           |
| June 2025      | Annual review and reference update                                                                                                           |
| December 2025  | Changed quantity limits to maximum mg per day                                                                                                |
| March 2026     | Annual review and reference update.                                                                                                          |
| April 2026     | Per SME, changed initiation wording for LFT and CBC monitoring                                                                               |
| June 2026      | Annual review and reference update                                                                                                           |

#### [Keywords](#)

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.**