

RATIONALE FOR INCLUSION IN PA PROGRAM

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



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VERZENIO (abemaciclib)

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).

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; November 2024.
2. NCCN Drugs & Biologics Compendium® Abemaciclib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 8, 2025.