

Verzenio (abemaciclib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Verzenio (abemaciclib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Verzenio (abemaciclib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2-) advanced or metastatic breast cancer; **AND**
 - II. One of the following criteria is met:
 - A. Individual is using as monotherapy for progression following endocrine therapy and prior chemotherapy in the metastatic setting (Label, NCCN 2A); **OR**
 - B. Individual is using in combination with an aromatase inhibitor for initial endocrine therapy (Label, NCCN 2A); **OR**
 - C. Individual is using in combination with fulvestrant as initial endocrine therapy (Label, NCCN 1); **OR**
 - D. Individual is using in combination with fulvestrant for progression following endocrine therapy (Label, NCCN 1);
- OR**
- III. Individual has a diagnosis of early breast cancer with HR+/HER2-, node positive cancer at high risk of recurrence (Label, NCCN 2A); **AND**
 - IV. Individual is using as adjuvant therapy in combination with endocrine therapy (tamoxifen or an aromatase inhibitor); **AND**
 - V. Individual is only using Verzenio in this combination for a total of 24 months (2 years).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. Verzenio (abemaciclib) [prescribing information]. Indianapolis, IN: Lilly USA, LLC; October 2021.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on March 30, 2021.
 - a. Breast Cancer. V4.2023. Revised March 23, 2023.
 - b. Soft Tissue Sarcoma. V1.2023. Revised March 13, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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