



# Evolut Clinical Guideline 3216 for Verzenio™ (abemaciclib)

<b>Guideline Number:</b> Evolut_CG_3216	<b><u>Applicable Codes</u></b>	
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## STATEMENT

### Purpose

To define and describe the accepted indications for Verzenio (abemaciclib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

## INDICATIONS

### Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

### Breast Cancer

- The member has node positive, ER/PR positive, HER2 negative high risk early-stage breast cancer (high risk is defined as any ONE of the following: greater than or equal to 4 positive axillary lymph nodes OR 1-3 nodes and either tumor size greater than or equal to 5 cm or histologic grade 3), AND Verzenio (abemaciclib) will be used in combination with tamoxifen or an aromatase inhibitor as adjuvant treatment for up to 2 years.
- The member has recurrent or metastatic breast cancer and ALL the following criteria:
  - Confirmed ER/PR positive and HER2 negative breast cancer AND
  - The member is postmenopausal OR is premenopausal treated with ovarian ablation/suppression (e.g., LHRH agonist) AND Verzenio (abemaciclib) will be used for any of the following criteria:
    - In combination with an aromatase inhibitor [i.e., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)] as first line therapy for recurrent unresectable/metastatic disease OR
    - In combination with Faslodex (fulvestrant) as subsequent therapy if CDK4/6 inhibitor [e.g., Kisqali (ribociclib), Ibrance (palbociclib)] was not previously used OR
    - As a single agent for disease progression following endocrine therapy (that did not include a CDK4/6 inhibitor) AND chemotherapy for metastatic disease.

## CONTRAINDICATIONS/WARNINGS

- None

## EXCLUSION CRITERIA

- Disease progression on or after prior therapy with Verzenio (abemaciclib), Ibrance (pablociclib), or Kisqali (ribociclib) containing regimens.
- Dosing exceeds single dose limit of Verzenio (abemaciclib) 200 mg (as monotherapy) or 150 mg (in combination with fulvestrant, tamoxifen, or an aromatase inhibitor).
- Treatment exceeds the maximum limit of 56 (50 mg), 56 (100 mg), 56 (150 mg), and 56 (200 mg) tablets/28 days.
- Investigational use of Verzenio (abemaciclib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
  - Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
  - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
  - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
  - That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

## CODING AND STANDARDS

### Codes

- J8999 - abemaciclib

### Applicable Lines of Business

<input type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

## POLICY HISTORY

Date	Summary
November 2025	<ul style="list-style-type: none"> <li>• Converted to new Evolent guideline template</li> <li>• This guideline replaces UM ONC_1328 Verzenio (abemaciclib)</li> <li>• Updated references</li> </ul>
November 2024	<ul style="list-style-type: none"> <li>• Updated maximum dosage form quantities in exclusion criteria</li> <li>• Updated references</li> </ul>

## LEGAL AND COMPLIANCE

### Guideline Approval

#### Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

### Disclaimer

*Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of*

*their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.*

## REFERENCES

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