# Clinical Policy: Abemaciclib (Verzenio)

Reference Number: CP.PHAR.355
Effective Date: 10.24.17
Last Review Date: 05.18
Line of Business: Commercial, Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

Abemaciclib (Verzenio®) is an inhibitor of cyclin-dependent kinases 4 and 6 (CDK4 and CDK6).

## FDA Approved Indication(s)

Verzenio is indicated:

- In combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.
- 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.
- In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

## Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Verzenio is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Breast Cancer** (must meet all):

1. Diagnosis of breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Disease meets all of the following characteristics (a, b, and c):
   a. HR-positive (i.e., estrogen receptor (ER) and/or progesterone receptor (PR) positive);
   b. HER2-negative;
   c. Disease is advanced (locally recurrent) or metastatic;
4. Age ≥ 18 years;
5. Verzenio is prescribed in one of the following ways (a, b, or c):
   a. In combination with fulvestrant after disease progression on an endocrine therapy;
   b. As a single agent after disease progression on an endocrine therapy and chemotherapy (e.g., docetaxel, gemcitabine, etc.);

c. In combination with an aromatase inhibitor as initial endocrine therapy;

6. Dose does not exceed one of the following (a or b):
   a. For combination therapy: 300 mg/day (two 150 mg tablets/day)
   b. For monotherapy: 400 mg/day (two 200 mg tablets/day).

**Approval duration:**
**Medicaid** – 6 months
**Commercial –** Length of Benefit

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

**A. Breast Cancer** (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Verzenio for breast cancer and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Dose is ≥ 100 mg/day;
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. For combination therapy: 300 mg/day (two 150 mg tablets/day);
   b. For monotherapy: 400 mg/day (two 200 mg tablets/day).

**Approval duration:**
**Medicaid** – 12 months
**Commercial –** Length of Benefit

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, and CP.PMN.53 for Medicaid.

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, and CP.PMN.53 for Medicaid or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

CDK: cyclin-dependent kinase
FDA: Food and Drug Administration

HER2: human epidermal growth factor receptor 2
HR: hormone receptor
ER: estrogen receptor
PR: progesterone receptor

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **Endocrine Therapy** | | |
| anastrozole (Arimidex®) | 1 mg PO QD | 1 mg/day |
| exemestane (Aromasin®) | 25 mg PO QD | 25 mg/day |
| Fareston® (toremifene) | 60 mg PO QD | 60 mg/day |
| Faslodex® (fulvestrant) | 500 mg IM into the buttocks slowly (1 - 2 minutes per injection) as two 5 mL injections, one in each buttock, on days 1, 15, 29 and once monthly thereafter | 500 mg/day |
| letrozole (Femara®) | 2.5 mg PO QD | 2.5 mg/day |
| tamoxifen (Nolvadex®, Soltamox®) | 20 to 40 mg PO QD | 40 mg/day |
| **Chemotherapy** | | |
| capecitabine (Xeloda®) | Various | Varies |
| carboplatin (Paraplatin®) | Various | Varies |
| cisplatin (Platinol-AQ®) | Various | Varies |
| cyclophosphamide (Cytoxan®) | Various | Varies |
| docetaxel (Taxotere®) | Various | Varies |
| doxorubicin (Lipodox®, Doxil®, Adriamycin®) | Various | Varies |
| epirubicin (Ellence®) | Various | Varies |
| gemcitabine (Gemzar®) | Various | Varies |
| Halaven® (eribulin) | Various | Varies |
| Ixempra® (ixabepilone) | Various | Varies |
| paclitaxel (Abraxane®, Taxol®) | Various | Varies |
| vinorelbine (Navelbine®) | Various | Varies |

*Drug names are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: General Information*
- Discontinue Verzenio for patients unable to tolerate 50 mg twice daily.

- Pre/perimenopausal women treated with the combination of Verzenio plus fulvestrant should be treated with a gonadotropin-releasing hormone agonist (e.g., goserelin) according to current clinical practice standards.
- For disease progression while on a CDK4 and CDK6 inhibitor, there is no data to support retreatment with another CDK4 and CDK6 inhibitor-containing regimen.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| In combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy. | 150 mg PO BID in combination with fulvestrant | 300 mg/day |
| 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. | 200 mg PO BID | 400 mg/day |
| Treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine based therapy. | 150 mg PO BID in combination with an aromatase inhibitor | 300 mg/day |

## VI. Product Availability

Tablet: 50 mg, 100 mg, 150 mg, and 200 mg

## VII. References

1. Verzenio Prescribing Information. Indianapolis, IN: Eli Lilly and Company; February 2018. Available at: http://pi.lilly.com/us/verzenio-uspi.pdf. Accessed March 20, 2018.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed March 05, 2018.
3. Goetz MP, Toi M, Campone M, et al. MONARCH 3: abemaciclib as initial therapy for advanced breast cancer. J Clin Oncol 2017; 35:3638-3646.
4. National Comprehensive Cancer Network. Breast Cancer Version 4.2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed February 27, 2018.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 10.24.17 | 11.17 |
| New indication added for initial endocrine therapy in combination with aromatase inhibitor for breast cancer; added specialist requirement. | 03.20.18 | 05.18 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.