Clinical Policy: Abemaciclib (Verzenio)

Reference Number: CP.PHAR.355
Effective Date: 12.01.17
Last Review Date: 11.26
Line of Business: Commercial, HIM/ICHRA, 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 (CDK4/6).

FDA Approved Indication(s)

Verzenio is indicated:

- 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.
- 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.
- In combination with fulvestrant for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.
- In combination with imlunestrant for the treatment of adults with estrogen receptor (ER)-positive, HER2-negative, estrogen receptor-1 (ESR1)-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least one line of 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.

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. Age ≥ 18 years;

4. Disease has both of the following characteristics (a and b):
   a. HR-positive (i.e., estrogen receptor (ER) and/or progesterone receptor (PR) positive);
   b. HER2-negative;
5. Verzenio is prescribed in one of the following ways (a or b):
   a. For advanced (including locally advanced), recurrent, or metastatic disease, one of the following (i, ii, iii, iv, or v):
      i. In combination with fulvestrant;
      ii. As a single agent after disease progression on an endocrine therapy and chemotherapy (e.g., docetaxel, gemcitabine) in the metastatic setting (*see Appendix B for examples*);
      iii. In combination with an aromatase inhibitor (e.g., letrozole, anastrozole, exemestane) as part of initial endocrine-based therapy;
      iv. In combination with Inluriyo® for ESR1-mutated disease after disease progression on endocrine therapy (*see Appendix B for examples*);
      v. In combination with Etcamah® for ESR1-mutated disease;
   b. For node-positive, early breast cancer with a high risk of recurrence, both (i and ii) of the following (*see Appendix D*):
      i. As adjuvant treatment;
      ii. In combination with endocrine therapy (tamoxifen or an aromatase inhibitor);
6. If male, prescribed in combination with an agent that suppresses testicular steroidogenesis (e.g., gonadotropin-releasing hormone agonists);
7. If prescribed as part of combination therapy and member is a premenopausal female, member has been treated with ovarian ablation or is receiving ovarian suppression (*see Appendix D*);
8. Member has not previously experienced disease progression on a CDK 4/6 inhibitor therapy (e.g., Ibrance®, Kisqali®);
9. Verzenio is not prescribed concurrently with another CDK 4/6 inhibitor therapy (e.g., Ibrance, Kisqali);
10. For brand name Verzenio requests, member must use generic abemaciclib, if available, unless contraindicated or clinically significant adverse effects are experienced;
11. Request meets one of the following (a or b):*
    a. Dose does not exceed one of the following (i or ii):
       i. For combination therapy: 300 mg per day (two 150 mg tablets per day);
       ii. For monotherapy: 400 mg per day (two 200 mg tablets per day);
    b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

    **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Endometrial Carcinoma (off-label) (must meet all)**:**
1. Diagnosis of endometrial carcinoma;
2. Prescribed by or in consultation with an oncologist;

3. Age ≥ 18 years;
4. Presence of ER-positive tumors;
5. Prescribed in combination with letrozole or fulvestrant;
6. Verzenio is not prescribed concurrently with another CDK 4/6 inhibitor therapy (e.g., Kisqali, Ibrance);
7. For brand Verzenio requests, member must use generic abemaciclib, if available, unless contraindicated or clinically significant adverse effects are experienced;
8. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

C. NCCN Recommended Uses (off-label) (must meet all)**:**
1. Diagnosis of one of the following (a or b):
   a. Dedifferentiated liposarcoma (a soft tissue sarcoma);
   b. Meningiomas (a central nervous system tumor);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent;
5. For meningiomas, both of the following (a and b):
   a. Disease is surgically inaccessible recurrent or progressive;
   b. Radiation is not possible;
6. Verzenio is not prescribed concurrently with another CDK 4/6 inhibitor therapy (e.g., Kisqali, Ibrance);
7. For brand Verzenio requests, member must use generic abemaciclib, if available, unless contraindicated or clinically significant adverse effects are experienced;
8. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

D. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the

relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Verzenio for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If breast cancer, dose is ≥ 100 mg per day;
4. Verzenio is not prescribed concurrently with another CDK 4/6 inhibitor therapy (e.g., Ibrance, Kisqali);
5. For brand name Verzenio requests, member must use generic abemaciclib, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed one of the following (i or ii):
      i. For combination therapy: 300 mg per day (two 150 mg tablets per day);
      ii. For monotherapy: 400 mg per day (two 200 mg tablets per day);
   b. New dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line

of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, 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, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CDK: cyclin-dependent kinase
ER: estrogen receptor
ESR1: estrogen receptor-1
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2
HR: hormone receptor
NCCN: National Comprehensive Cancer Network
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
Breast Cancer		
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
megestrol acetate	40 mg PO QID	160 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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: Contraindications/Boxed Warnings
None reported

Appendix D: General Information
- High risk breast cancer is defined by the NCCN as those with ≥ 4 positive lymph nodes (confirmed preoperatively and/or at surgery), or 1–3 positive lymph nodes with either grade 3 disease or tumor size ≥ 5 cm (on pre-operative imaging and/or at surgery).
- NCCN recommendations in breast cancer:
  - The NCCN recommends that men with breast cancer be treated similarly to postmenopausal women, except that the use of an aromatase inhibitor is ineffective without concomitant suppression of testicular steroidogenesis.
  - The NCCN supports use of Verzenio in premenopausal women when used concomitantly with an aromatase inhibitor or fulvestrant. Along with this combination therapy, patients should also be treated with ovarian ablation/suppression. Ovarian ablation can be achieved with surgical oophorectomy or ovarian irradiation. Ovarian suppression can be achieved with luteinizing hormone-releasing hormone agonists (e.g., goserelin, leuprolide).
  - Although the FDA labeled indication limits combination use with fulvestrant to second line, the NCCN recommends this combination as both first and second line.
- For disease progression while on a CDK4/6 inhibitor, there is no data to support retreatment with another CDK4/6 inhibitor-containing regimen.

V. Dosage and Administration

Indication	Dosing Regimen*	Maximum Dose
Breast cancer	In combination with fulvestrant, tamoxifen, imlunestrant, or an aromatase inhibitor: 150 mg PO BID As monotherapy: 200 mg PO BID	Combination therapy: 300 mg/day Monotherapy: 400 mg/day

**If a dose reduction to < 100 mg/day is required, therapy should be discontinued.*

VI. Product Availability
Tablets: 50 mg, 100 mg, 150 mg, 200 mg

VII. References

1. Verzenio Prescribing Information. Indianapolis, IN: Eli Lilly and Company; September 2026. Available at: http://www.verzenio.com. Accessed September 23, 2026.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed August 7, 2026.
3. National Comprehensive Cancer Network. Breast Cancer Version 7.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed September 28, 2026.
4. National Comprehensive Cancer Network. Uterine Neoplasms Version 3.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed August 8, 2026.
5. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 5.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed August 8, 2026.
6. National Comprehensive Cancer Network. Meningiomas Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed August 10, 2026.
7. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed September 23, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2022 annual review: no significant changes; WCG-specific policy was retired and that approval duration was consolidated to 6 months for the initial authorization; references reviewed and updated. Template changes applied to other diagnoses/indications.	06.21.22	11.22
RT4: updated indications for early breast cancer to remove Ki-67 score requirement and for advanced or metastatic breast cancer indication to replace postmenopausal women and men with adults per FDA-labeling.	03.15.23	
4Q 2023 annual review: no significant changes; added NCCN definition of high-risk breast cancer for Verzenio use as adjuvant therapy to Appendix D; references reviewed and updated.	08.12.23	11.23
4Q 2024 annual review: added criteria for endometrial carcinoma as off-label indication is supported by NCCN compendium and guidelines; for Appendix D, updated high risk breast cancer definition to align with NCCN compendium; references reviewed and updated.	07.15.24	11.24
4Q 2025 annual review: added criteria for soft tissue sarcoma as off-label indication is supported by NCCN compendium and guidelines; for initial approval criteria, extended approval duration from 6 months to 12 months for HIM and Medicaid; for endometrial carcinoma initial therapy, added "12 months or duration of request, whichever is less" for commercial; references reviewed and updated.	07.10.25	11.25
4Q 2026 annual review: for breast cancer, added use in combination with Inluriyo after disease progression on endocrine therapy for advanced, recurrent, or metastatic disease supported by NCCN;	09.29.26	11.26

Reviews, Revisions, and Approvals	Date	P&T Approval Date
added if disease is ESR1 mutated, prescribed in combination with Etcamah per Etcamah's FDA labeled indication; for endometrial carcinoma, added option to be prescribed in combination with fulvestrant per NCCN; added off-label criteria for meningiomas per NCCN; added ICHRA line of business; references reviewed and updated. RT4: updated FDA approved indications section to add combination use with imlunestrant; for breast cancer, updated criterion for combination use with imlunestrant for ESR1-mutated disease.		

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.

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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.

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