Generic Name: abemaciclib

Therapeutic Class or Brand Name: Verzenio

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/26/2019

Date Last Reviewed / Revised: 4/25/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VI are met)

I. Documentation of the following diagnosis AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Breast Cancer

1. Documentation disease is hormone-receptor (HR)-positive
2. Documentation disease is human epidermal growth factor receptor 2 (HER2)-negative and meets ONE of the following criteria a or b:

a) Early Breast Cancer

(1) Documentation of node-positive disease at high risk of recurrence.

(2) Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor [see Appendix]).

b) Advanced or metastatic breast cancer and meets ONE of the following criteria (1) or (2):

(1) Documentation of no prior endocrine therapy.

(a) Verzenio will be used in combination with an aromatase inhibitor (see Appendix).

(2) Documentation of disease progression following endocrine therapy and meets ONE of the following criteria a or b:

(a) Verzenio will be used in combination with fulvestrant (Faslodex).

(b) Disease has progressed after at least 1 chemotherapy regimen for metastatic disease.

(i) Verzenio will be used as monotherapy.

Other Uses With Supportive Evidence

B. Endometrial Carcinoma

1. Documentation of recurrent or metastatic disease

2. Documentation of estrogen receptor (ER)-positive disease
3. Used in combination with letrozole

II. The patient has had no prior treatment with a CDK 4/6 inhibitor (i.e. Verzenio [abemaciclib], Ibrance [palbociclib], Kisqali [ribociclib]) resulting in disease progression.

III. Minimum age requirement: 18 years old.

IV. Treatment must be prescribed by or in consultation with an oncologist.

V. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VI. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- Pre/peri-menopausal women and men treated with the combination of Verzenio plus aromatase inhibitor should be treated with a gonadotropin-releasing hormone agonist (GnRH) (e.g., Zoladex [goserelin], Lupron [leuprolide], etc.).
- Pre/peri-menopausal women treated with the combination of Verzenio plus fulvestrant (Faslodex) should be treated with a gonadotropin-releasing hormone agonist (GnRH) (e.g., Zoladex [goserelin], Lupron [leuprolide], etc.).

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities of up to 60 tablets per 30 days.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease. For diagnosis of HR+, HER2-, node positive, early breast cancer: duration of treatment does not exceed 2 years.

APPENDIX

Endocrine Therapies used in HR+, HER2- breast cancer

Estrogen Agonist/Antagonists	Aromatase inhibitors
Tamoxifen	Anastrazole
Fulvestrant	Letrozole
Toremifene	Exemestane

REFERENCES

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Breast Cancer. Version 4.2025. Updated April 17, 2025. Accessed April 25, 2025. www.nccn.org/professionals/physician_gls/pdf/breast.pdf
2. Verzenio. Prescribing Information. Lilly USA, LLC. February 2025. Accessed April 25, 2025. www.accessdata.fda.gov/drugsatfda_docs/label/2025/208716s019lbl.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Uterine Neoplasms. Version 3.2025. Updated March 7, 2025. Accessed April 25, 2025. www.nccn.org/professionals/physician_gls/pdf/breast.pdf