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: 11/9/2023

PRIOR AUTHORIZATION CRITERIA

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

I. Documented diagnosis of one of the following conditions A OR B AND must meet criteria listed under applicable diagnosis:

   A. Documented diagnosis of hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-), advanced or metastatic breast cancer and one of the following criteria 1 through 3 are met:

      1. The patient has had no prior endocrine therapy and the following criteria are met:

         a. The patient is postmenopausal.

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

      2. Documented disease progression following treatment with prior endocrine therapy and the following criterion is met:

         a. Verzenio will be used in combination with fulvestrant.

      3. Documented disease progression following treatment with prior endocrine therapy and prior chemotherapy and the following criteria are met:

         a. Chemotherapy regimen was administered in the metastatic setting.

         b. Verzenio will be used as monotherapy.

   B. Documented diagnosis of hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-), node positive, early breast cancer at high risk of recurrence and meets the following criteria:

      1. Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor).

II. The patient has had no prior treatment with a CDK 4/6 inhibitor (i.e. abemaciclib, palbociclib, 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

- N/A

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 that the medication is effective. 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. NCCN Clinical Practice Guidelines in Oncology. Breast Cancer v.4.2023. Updated March 23, 2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf.
2. Verzenio® [Package insert] Indianapolis, IN: Lilly USA; October 2021. Available at: http://pi.lilly.com/us/verzenio-uspi.pdf.