Reference number(s)
2342-A

SPECIALTY GUIDELINE MANAGEMENT

VERZENIO (abemaciclib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Verzenio is indicated:
1. Early Breast Cancer
    a. 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 and a Ki-67 score ≥20% as determined by an FDA approved test.
2. Advanced or Metastatic Breast Cancer
    a. In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.
    b. 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.
    c. 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.

B. Compendial Uses
Breast cancer: Therapy for recurrent HR-positive, HER2-negative disease.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Documentation of laboratory results confirming hormone receptor (HR) status
B. Documentation of laboratory results confirming HER2 status
C. Documentation of test results confirming Ki-67 score, where applicable

III. CRITERIA FOR INITIAL APPROVAL

Breast Cancer
Authorization of 12 months may be granted for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer when either of the following criteria is met:
1. Member has early breast cancer and all of the following:
    a. The requested medication is used as adjuvant treatment

   b. The requested medication is used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor)
   c. Member has node positive disease
   d. The Ki-67 score is 20% or greater
2. Member has recurrent, advanced, or metastatic breast cancer and the requested medication is used in any of the following regimens:
   a. As monotherapy for a member who has experienced disease progression following endocrine therapy and prior chemotherapy in the metastatic setting; or
   b. In combination with fulvestrant; or
   c. In combination with an aromatase inhibitor (e.g., letrozole, anastrazole, exemestane).

IV. CONTINUATION OF THERAPY

A. Early Breast Cancer

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for early breast cancer until completion of 2 years of treatment or until disease recurrence or unacceptable toxicity while on the current regimen.

B. Recurrent, Advanced, or Metastatic Breast Cancer

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for recurrent, advanced, or metastatic breast cancer when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Verzenio [package insert]. Indianapolis, IN: Eli Lilly and Company; October 2021.
2. The NCCN Drugs & Biologics Compendium © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed November 24, 2020.
3. Dickler MN, Tolaney SM, Rugo HS, et al. MONARCH 1, a phase II study of abemaciclib, a CDK4 and CDK6 inhibitor, as a single agent, in patients with refractory HR+/HER2- metastatic breast cancer. *Clin Cancer Res.* 2017;23(17):5218-5224.
4. Sledge, GW Jr, Toi M, Neven P, et al. MONARCH 2: abemaciclib in combination with fulvestrant in women with HR+/HER2- advanced breast cancer who had progressed while receiving endocrine therapy. *J Clin Oncol*. 2017;35(25):2875-2884.