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.
2. Advanced or Metastatic Breast Cancer
   a. 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.
   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
1. Breast cancer: Therapy for recurrent HR-positive, HER2-negative disease.
2. Endometrial carcinoma

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. For members requesting initiation of therapy for the treatment of breast cancer: documentation of laboratory results confirming hormone receptor (HR) status and HER2 status
B. For members requesting initiation of therapy for the treatment of endometrial carcinoma: results of estrogen receptor status

III. CRITERIA FOR INITIAL APPROVAL

A. Breast Cancer
1. Authorization of 12 months may be granted for the treatment of HR-positive, HER2-negative, early breast cancer when all of the following criteria are met:
   a. The requested medication is used as adjuvant treatment, in combination with endocrine therapy (tamoxifen or an aromatase inhibitor)

b. The member has either:
   i. Four or more positive lymph nodes; or
   ii. One to three positive lymph nodes and at least one of the following: grade 3 disease or tumor size of 5 cm or greater

2. Authorization of 12 months may be granted for the treatment of HR-positive, HER2-negative, 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).

B. Endometrial Carcinoma
Authorization of 12 months may be granted for the treatment of advanced, recurrent, or metastatic endometrial carcinoma with estrogen receptor positive tumors when used in combination with letrozole.

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, or Endometrial Carcinoma
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for recurrent, advanced, or metastatic breast cancer or endometrial carcinoma 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; May 2023.
2. The NCCN Drugs & Biologics Compendium © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed November 1, 2023.
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.