| Reference number(s) |
| --- |
| 2342-A |

# Specialty Guideline Management
# Verzenio

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Verzenio | abemaciclib |

## 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.

### FDA-Approved Indications[1]

Verzenio is indicated:

- Early Breast Cancer
  - 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.
- Advanced or Metastatic Breast Cancer
  - 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.


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- 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.

## Compendial Uses[2-5]

- Breast cancer
- Endometrial carcinoma
- Liposarcoma

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

# Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Documentation of laboratory results confirming hormone receptor (HR) status and HER2 status, where applicable.
- Documentation of laboratory results confirming estrogen receptor 1 (ESR1) status, where applicable.
- Documentation of laboratory results confirming results of estrogen receptor (ER) status, where applicable.

# Coverage Criteria

## Breast Cancer[1-4,6]

Authorization of 12 months may be granted for the adjuvant treatment of HR-positive, HER2-negative breast cancer when all of the following criteria are met:

- The requested medication will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor).
- The member has high risk disease and either of the following is met:
  - Four or more positive lymph nodes
  - One to three positive lymph nodes and at least one of the following:
    - Grade 3 disease
    - Tumor size of 5 cm or greater


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Authorization of 12 months may be granted for the treatment of HR-positive, HER2-negative, breast cancer when one of the following criteria is met:

- Member has recurrent unresectable or metastatic disease and the requested medication is used in any of the following regimens:
    - As monotherapy for a member who has experienced disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.
    - In combination with fulvestrant.
    - In combination with an aromatase inhibitor (e.g., letrozole, anastrazole, exemestane).
    - As subsequent therapy in combination with Inluriyo (imlunestrant) and member has ESR1-mutated disease.
- Member has ESR1-mutated locally advanced or metastatic disease and the requested medication with be used in combination with Etcamah (camizestrant).

Authorization of 12 months may be granted for the treatment of ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer when used in combination with Inluriyo (imlunestrant) and the member has experienced disease progression following at least one line of endocrine therapy.

## Endometrial Carcinoma[2,5]

Authorization of 12 months may be granted for the treatment of recurrent or metastatic endometrial carcinoma with estrogen receptor (ER) positive tumors when used in combination with letrozole or fulvestrant.

Authorization of 12 months may be granted to members for adjuvant treatment of stage IV endometrial carcinoma with ER-positive tumors when used in combination with letrozole or fulvestrant.

## Liposarcoma[2]

Authorization of 12 months may be granted for the treatment of dedifferentiated liposarcoma as a single agent.

# Continuation of Therapy

## Adjuvant Breast Cancer Treatment

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


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## Recurrent Unresectable or Metastatic Breast Cancer, Endometrial Carcinoma, or Liposarcoma

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

# References

1. Verzenio [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2026.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed September 15, 2026.
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.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms. Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed November 18, 2025.
6. Etcamah [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2026.


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