

## Verzenio™ (abemaciclib) (Oral)

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### I. Length of Authorization

Coverage is provided for six months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- All strengths: 1 tablet twice daily

#### B. Max Units (per dose and over time) [Medical Benefit]:

- 400 mg daily

### III. Initial Approval Criteria

- Patient is at least 18 years old; **AND**
- Patient has not received previous therapy with a cyclin-dependent kinase (CDK) 4 and 6 inhibitor (e.g., palbociclib, ribociclib, etc.); **AND**

Coverage is provided in the following conditions:

#### Breast Cancer †

- Patient's disease is hormone receptor (HR)-positive; **AND**
- Patient's disease is human epidermal growth factor receptor 2 (HER2)-negative; **AND**
- Patient has advanced, recurrent or metastatic disease; **AND**
  - Used as initial endocrine based therapy in combination with an aromatase inhibitor (e.g., letrozole); **AND**
    - Patient is a postmenopausal woman; **OR**
    - Patient is a premenopausal woman receiving ovarian suppression with a gonadotropin-releasing hormone agonist; **OR**
    - Patient is a male receiving androgen deprivation therapy (ADT); **OR**

- Used in combination with fulvestrant following disease progression on endocrine therapy; **AND**
  - Patient is a post-menopausal woman; **OR**
  - Patient is a premenopausal woman receiving ovarian suppression with a gonadotropin-releasing hormone agonist; **OR**
  - Patient is a male and receiving ADT; **OR**
- Used as a single agent; **AND**
  - Patient progressed on prior endocrine therapy and prior chemotherapy; **AND**
  - Patient is a post-menopausal women or male receiving ADT

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s)

#### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Request continues to meet the criteria identified in section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: Grade 3 or 4 diarrhea, neutropenia, hepatotoxicity, venous thromboembolism, etc.

#### V. Dosage/Administration

Indication	Dose
Breast Cancer	<p><u>Combination Therapy:</u></p> <ul style="list-style-type: none"> <li>• 150 mg orally twice daily</li> </ul> <p>(Fulvestrant 500 mg is administered on Days 1, 15, 29, &amp; monthly thereafter; aromatase inhibitors are administered according to the labeling for the agent)</p> <p><u>Monotherapy:</u></p> <ul style="list-style-type: none"> <li>• 200 mg orally twice daily</li> </ul>

#### VI. Billing Code/Availability Information

HCPCS-code:

J8999 - Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

C9399 - Unclassified drugs or biologicals, (*Hospital Outpatient Use ONLY*)

NDC:

- Verzenio 200 mg dose pack (14 tablets): 00002-6216-xx
- Verzenio 150 mg dose pack (14 tablets): 00002-5337-xx

- Verzenio 100 mg dose pack (14 tablets): 00002-4815-xx
- Verzenio 50 mg dose pack (14 tablets): 00002-4483-xx

## VII. References

1. Verzenio [package insert]. Indianapolis, IN; Eli Lilly and Company; February 2018. Accessed June 2018.
2. 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 Sep 1;23(17):5218-5224. doi: 10.1158/1078-0432.CCR-17-0754.
3. 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 Sep 1;35(25):2875-2884. doi: 10.1200/JCO.2017.73.7585.
4. Goetz MP, Toi M, Campone M, et al. MONARCH 3: Abemaciclib As Initial Therapy for Advanced Breast Cancer. *J Clin Oncol.* 2017 Nov 10;35(32):3638-3646. doi: 10.1200/JCO.2017.75.6155.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for abemaciclib. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2018.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast

C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast

**VERZENIO™ (abemaciclib) Prior Auth Criteria**

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C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of breast (male)
C50.922	Malignant neoplasm of breast (male)
C50.929	Malignant neoplasm of breast (male)
Z85.3	Personal history of malignant neoplasm of breast

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC