

Verzenio™ (abemaciclib) (Oral)

Document Number: IC-0323

Last Review Date: 08/04/2020

Date of Origin: 10/31/2017

Dates Reviewed: 10/2017, 03/2018, 08/2018, 08/2019, 08/2020

I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- All strengths: 1 tablet twice daily

B. Max Units (per dose and over time) [HCPCS Unit]:

- 400 mg daily

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ¹

- Patient has not received previous therapy with a cyclin-dependent kinase (CDK) 4 and 6 inhibitor (e.g., palbociclib, ribociclib, etc.); **AND**
- Patient will avoid concomitant therapy with all of the following:
 - Patient will avoid concomitant use with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
 - Patient will avoid concomitant use with strong and CYP3A inhibitors (e.g., fluconazole, clarithromycin, erythromycin, grapefruit, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
 - Patient will avoid concomitant use with ketoconazole; **AND**

Breast Cancer † ¹⁻⁶

- Patient has hormone receptor (HR)-positive disease; **AND**

- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
- Patient has advanced, recurrent, or metastatic disease; **AND**
- Patient does not have visceral crisis; **AND**
 - Patient is a male and receiving androgen deprivation therapy (ADT); **OR**
 - Patient is a postmenopausal woman; **OR**
 - Patient is a premenopausal woman receiving ovarian ablation/suppression (e.g., surgical ablation, suppression with a gonadotropin-releasing hormone agonist, etc.); **AND**
- Therapy is being use as one of the following:
 - As initial endocrine based therapy in combination with an aromatase inhibitor (e.g., letrozole); **OR**
 - Used in combination with fulvestrant as initial endocrine based therapy OR as subsequent therapy after disease progression on or after endocrine therapy; **OR**
 - Used as a single agent after progression on endocrine therapy and chemotherapy in the metastatic setting

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

IV. Renewal Criteria ¹⁻⁶

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria identified in section III; **AND**
- Disease response with treatment as defined by 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, severe interstitial lung disease/pneumonitis, etc.

V. Dosage/Administration ¹

| Indication | Dose |
|---------------|--|
| Breast Cancer | <p><u>Combination Therapy:</u></p> <ul style="list-style-type: none"> • 150 mg orally twice daily <p>(Fulvestrant 500 mg is administered on Days 1, 15, 29, & 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"> • 200 mg orally twice daily |

VI. Billing Code/Availability Information

HCPSC-code:

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

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; March 2020. Accessed June 2020.
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, 2020. 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 2020.
6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer 4.2020. National Comprehensive Cancer Network, 2020. 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 Guidelines, go online to NCCN.org. Accessed June 2020.

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 |
| 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), Local Coverage Determinations (LCDs), and Local Coverage Article (LCAs) 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/LCA): 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 |

Medicare Part B Administrative Contractor (MAC) Jurisdictions

| Jurisdiction | Applicable State/US Territory | Contractor |
|--------------|---|---|
| 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 | Palmetto GBA, 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 |