Verzenio™ (abemaciclib)
(Oral)

Document Number: IC-0323

Last Review Date: 08/08/2023
Date of Origin: 10/31/2017
Dates Reviewed: 10/2017, 03/2018, 08/2018, 08/2019, 08/2020, 08/2021, 11/2021, 08/2022, 08/2023

I. Length of Authorization [1]

Coverage is provided for six (6) months and may be renewed (unless otherwise specified).

- Adjuvant treatment of early breast cancer can be authorized up to a maximum of two (2) years of therapy.

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:
  - Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with strong and moderate CYP3A4 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**
  - Coadministration with ketoconazole; **AND**

Breast Cancer † ‡ [1-7]

- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
- Patient has hormone receptor (HR)-positive disease; **AND**
    - Used for recurrent unresectable (local or regional), advanced, or metastatic disease; **AND**
        - Patient has no visceral crisis; **AND**
        - Patient is postmenopausal, premenopausal with ovarian ablation/suppression, or male with suppression of testicular steroidogenesis; **AND**
            - Used as initial therapy in combination with a non-steroidal aromatase inhibitor (i.e., anastrozole, letrozole, etc.) or fulvestrant; **OR**
            - Used as subsequent therapy in combination with fulvestrant; **OR**
            - Used as a single agent after progression on prior endocrine therapy and chemotherapy in the metastatic setting; **OR**
    - Used as adjuvant treatment of early breast cancer; **AND**
        - Patient has high risk disease as defined by one of the following:
            - Patient has ≥4 positive lymph nodes; **OR**
            - Patient has 1-3 positive lymph nodes with one or more of the following: Grade 3 disease or tumor size ≥5 cm; **AND**
        - Used in combination with endocrine therapy (i.e., tamoxifen or an aromatase inhibitor)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,5,6]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. 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: Grade 3 or 4 diarrhea, neutropenia, hepatotoxicity, venous thromboembolism, severe interstitial lung disease/pneumonitis, etc.

Breast Cancer (adjuvant treatment)

- Patient has not exceeded a maximum of two (2) years of therapy

V. Dosage/Administration [1]

Indication	Dose
Breast Cancer (recurrent unresectable, advanced, or metastatic disease)	Combination Therapy: • Administer 150 mg orally twice daily until disease progression or unacceptable toxicity. *(Refer to the Full Prescribing Information for the recommended dose of fulvestrant or aromatase inhibitor being used)* Monotherapy: • Administer 200 mg orally twice daily until disease progression or unacceptable toxicity.
Breast Cancer (adjuvant treatment)	Administer 150 mg orally twice daily until completion of 2 years of treatment or until disease recurrence or unacceptable toxicity. *(Refer to the Full Prescribing Information for the recommended dose of tamoxifen or aromatase inhibitor being used)*

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC(s):

- 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 2023. Accessed June 2023.
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, 2023. 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 2023.
6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer 4.2023. National Comprehensive Cancer Network, 2023. 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 2023.
7. Johnston SRD, Harbeck N, Hegg R, et al.; monarchE Committee Members and Investigators. Abemaciclib Combined With Endocrine Therapy for the Adjuvant Treatment of HR+, HER2-, Node-Positive, High-Risk, Early Breast Cancer (monarchE). J Clin Oncol. 2020 Dec 1;38(34):3987-3998. doi: 10.1200/JCO.20.02514.

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)

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: https://www.cms.gov/medicare-coverage-database/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
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