Drug Policy:

Verzenio™ (abemaciclib)

POLICY NUMBER UM ONC_1328	SUBJECT Verzenio™ (abemaciclib)		DEPT/PROGRAM UM Dept	PAGE 1 of 3
DATES COMMITTEE REVIEWED 10/11/17, 10/10/18, 10/09/19, 12/11/19, 09/11/20, 08/11/21, 09/08/21, 11/15/21, 12/08/21, 05/11/22, 08/10/22, 06/14/23, 6/12/24, 11/13/24	APPROVAL DATE November 13, 2024	EFFECTIVE DATE November 29, 2024	COMMITTEE APPROVAL DATES 10/11/17, 10/10/18, 10/09/19, 12/11/19, 09/11/20, 08/11/21, 09/08/21, 11/15/21, 12/08/21, 05/11/22, 08/10/22, 06/14/23, 06/12/24, 11/13/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Evolent Specialty Services Clinical Guideline Review Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Verzenio (abemaciclib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Breast Cancer

1. The member has node positive, ER/PR positive, HER2 negative high risk early-stage breast cancer (high risk is defined as any ONE of the following: greater than or equal to 4 positive axillary lymph nodes OR 1-3 nodes and either tumor size greater than or equal to 5 cm or histologic grade 3 AND Verzenio (abemaciclib) will be used in combination with tamoxifen or an aromatase inhibitor as adjuvant treatment for up to 2 years.

2. The member has recurrent or metastatic breast cancer and of ALL the following criteria:
    a. Confirmed ER/PR positive and HER2 negative breast cancer AND
    b. The member is postmenopausal OR is premenopausal treated with ovarian oblation/suppression (e.g., LHRH agonist) AND Verzenio (abemaciclib) will be used for any of the following criteria:
        i. In combination with an aromatase inhibitor [i.e., Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)] as first line therapy for recurrent unresectable/metastatic disease OR
        ii. In combination with Faslodex (fulvestrant) as subsequent therapy if CDK4/6 inhibitor [e.g., Kisqali (ribociclib), Ibrance (palbociclib)] was not previously used OR
        iii. As a single agent for disease progression following endocrine therapy (that did not include a CDK4/6 inhibitor) AND chemotherapy for metastatic disease.

III. EXCLUSION CRITERIA

A. Disease progression on or after prior therapy with Verzenio (abemaciclib), Ibrance (pablociclib), or Kisqali (ribociclib) containing regimens.

B. Dosing exceeds single dose limit of Verzenio (abemaciclib) 200 mg (as monotherapy) or 150 mg (in combination with fulvestrant, tamoxifen, or an aromatase inhibitor).

C. Treatment exceeds the maximum limit of 56 (50 mg), 56 (100 mg), 56 (150 mg), and 56 (200 mg) tablets/28 days.

D. Investigational use of Verzenio (abemaciclib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
    1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
    4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
    5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
    6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
    7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

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A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Johnston SRD, et al. 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.

B. Johnston S, et al. MONARCH 3 final PFS: a randomized study of abemaciclib as initial therapy for advanced breast cancer. NPJ Breast Cancer. 2019 Jan 17;5:5.

C. Sledge GW Jr, et al, The Effect of Abemaciclib Plus Fulvestrant on Overall Survival in Hormone Receptor-Positive, ERBB2-Negative Breast Cancer That Progressed on Endocrine Therapy-MONARCH 2: A Randomized Clinical Trial. JAMA Oncol. 2020 Jan 1;6(1):116-124.

D. Verzenio prescribing information. Lilly USA, LLC, Indianapolis, IN 2024.

E. Clinical Pharmacology Elsevier Gold Standard 2024.

F. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2024.

G. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.

H. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2024.

I. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

J. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

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