Drug Policy:

Verzenio™ (abemaciclib)

POLICY NUMBER UM ONC_1328	**SUBJECT** Verzenio™ (abemaciclib)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
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	**APPROVAL DATE** August 10, 2022	**EFFECTIVE DATE** August 26, 2022	**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	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	**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.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways (http://pathways.newcenturyhealth.com/) when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs AND
6. When there is a documented drug shortage, disease progression, contraindication, or confirmed intolerance to a Preferred drug/regimen, per NCH Policy and Pathway, the available alternative product may be used if deemed medically appropriate and the indication is listed in a standard reference compendia or accepted peer review literature. For a list of current drug shortages, please refer to FDA drug shortage website in the reference section.

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: ≥4 positive axillary lymph nodes OR 1-3 nodes and either tumor size ≥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: [B]
   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 OR
      ii. In combination with Faslodex (fulvestrant) as first line or 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 240 (50 mg), 120 (100 mg), 60 (150 mg), and 60 (200 mg) tablets/month.

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 definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, in light of 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

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 2021.

E. Clinical Pharmacology Elsevier Gold Standard 2022.

F. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2022.

G. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2022.

H. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2022.

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.

K. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

L. NCQA UM 2022 Standards and Elements.