Drug Policy:

Ibrance™ (palbociclib))

POLICY NUMBER UM ONC_1272	SUBJECT Ibrance™ (palbociclib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 03/27/15, 05/24/16, 07/26/17, 07/19/18, 06/13/19, 12/11/19, 03/11/20, 09/11/20	APPROVAL DATE September 11, 2020	EFFECTIVE DATE September 25, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 03/27/15, 05/24/16, 07/26/17, 07/19/18, 06/13/19, 12/11/19, 03/11/20, 09/11/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 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 Ibrance (palbociclib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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 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 available, generic alternatives are preferred over brand-name drugs.

B. Breast Cancer

1. Note: Per NCH policies and NCH L1 Pathways, Verzenio (abemaciclib)/Kisqali (ribociclib) are the preferred CDK4/6 inhibitors for postmenopausal women or premenopausal woman treated with ovaria oblation/suppression with advanced/metastatic breast cancer in the following settings. *Please refer to UM ONC_1328 for Verzenio™ (abemaciclib) and UM ONC_1310 for Kisqali™ (ribociclib) policies:*
    a. In combination with an aromatase inhibitor as first line therapy OR
    b. In combination with fulvestrant or as a single agent as subsequent therapy.
2. The member has recurrent or metastatic breast cancer and Ibrance (palbociclib) is being used for ALL of the following:
    a. Member has ER/PR positive and HER2 negative breast cancer
    b. Member is a postmenopausal woman, OR, a premenopausal woman receiving concurrent ovarian ablation/suppression, OR a male with breast cancer AND
3. Ibrance (palbociclib is being used in combination with aromatase inhibitor OR in combination with Faslodex (fulvestrant).

III. EXCLUSION CRITERIA

A. Disease progression while taking Ibrance (palbociclib) OR another CDK4/6 inhibitor (e.g. Ribociclib or Abemaciclib).

B. Dosing exceeds single dose limit of Ibrance (palbociclib) 125 mg.

C. Treatment exceeds the maximum limit of 21 (125 mg, 100 mg, or 75 mg) tablets/month.

D. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature. reimbursable.

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. Ibrance prescribing information. Pfizer Laboratories Div Pfizer, Inc . NY, NY. 2019.

B. Clinical Pharmacology Elsevier Gold Standard. 2020.

C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.

D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.

E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.