

<b>POLICY NUMBER</b> UM_ONC_1272	<b>SUBJECT</b> Ibrance™ (palbociclib)	<b>DEPT/PROGRAM</b> UM Dept	<b>PAGE 1 OF 2</b>
<b>DATE REVIEWED</b> 03/27/15, 05/24/16, 07/26/17, 07/19/18, 06/13/19, 12/11/19, 03/11/20	<b>APPROVAL DATE</b> March 11, 2020	<b>EFFECTIVE DATE</b> March 27, 2020	<b>REVISION DATES</b> (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
<b>PRIMARY BUSINESS OWNER: UM</b> <b>APPROVED BY:</b> Dr. Andrew Hertler		<b>COMMITTEE/BOARD APPROVAL</b> Utilization Management Committee	
<b>URAC STANDARDS</b> HUM 1		<b>NCQA STANDARDS</b> UM 2	<b>ADDITIONAL AREAS OF IMPACT</b>
<b>CMS REQUIREMENTS</b>	<b>STATE/FEDERAL REQUIREMENTS</b>		<b>APPLICABLE LINES OF BUSINESS</b> All

## 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 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

### 1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- 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**
- 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**
- 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: <http://pathways.newcenturyhealth.com> **AND**
- Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- When available, generic alternatives are preferred over brand-name drugs.

### 2. Breast Cancer

- NOTE: The preferred regimen, per NCH Policies and NCH Pathways, for first and subsequent line of therapy of recurrent/metastatic endocrine-responsive & HER-2 negative breast cancer is [Palbociclib + Aromatase Inhibitor].
- The member has recurrent or metastatic breast cancer and Ibrance (palbociclib) is being used for **ALL** of the following:



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- i. Member has ER/PR positive and HER2 negative breast cancer
- ii. Member is a postmenopausal woman, OR, a premenopausal woman receiving concurrent ovarian ablation/suppression, OR a male with breast cancer

**AND**

- c. Ibrance (palbociclib) is being used in combination with aromatase inhibitor **OR** in combination with Faslodex (fulvestrant).

### III. EXCLUSION CRITERIA

- 1. Off-label indications for Ibrance (palbociclib) in soft tissue sarcoma shall be reviewed for appropriateness per National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or other compelling medical literature publications.
- 2. Disease progression while taking Ibrance (palbociclib), OR another CDK4/6 inhibitor (e.g. Ribociclib or Abemaciclib).
- 3. Dosing exceeds single dose limit of Ibrance (palbociclib) 125 mg.
- 4. Treatment exceeds the maximum limit of 21 (125 mg, 100 mg, or 75 mg) tablets/month.
- 5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature. reimbursable.

### IV. MEDICATION MANAGEMENT

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

### V. APPROVAL AUTHORITY

- 1. Review – Utilization Management Department
- 2. Final Approval – Utilization Management Committee

### VI. ATTACHMENTS

None

### VII. REFERENCES

- 1. Ibrance prescribing information. Pfizer Laboratories Div Pfizer, Inc. NY, NY. 2019.
- 2. Clinical Pharmacology Elsevier Gold Standard. 2020.
- 3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
- 4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
- 5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.