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| POLICY NUMBER UM_ONC_1360 | SUBJECT Piqray™ (alpelisib) | DEPT/PROGRAM UM Dept | PAGE 1 OF 2 |
| DATES COMMITTEE REVIEWED 06/12/19, 12/11/19, 06/10/20 | APPROVAL DATE June 10, 2020 | EFFECTIVE DATE June 26, 2020 | COMMITTEE APPROVAL DATES (latest version listed last) 06/12/19, 12/11/19, 06/10/20 |
| 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 All | |

I. PURPOSE

To define and describe the accepted indications for Piqray (alpelisib) 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 **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

- Piqray (alpelisib) may be used if ALL the following criteria are satisfied:
 - Member (includes both men and women- postmenopausal or premenopausal and receiving concurrent ovarian suppression) has ER/PR positive and HER-2 negative metastatic/advanced breast cancer **AND**
 - Member's cancer is positive for a PIK3CA- mutation, confirmed by tissue biopsy and/or liquid biopsy either by the companion diagnostic therascreen PIK3CA mutation test OR another valid equivalent test) **AND**
 - Piqray (alpelisib) will be used in combination with fulvestrant **AND**



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- iv. Member has experienced disease progression on or after therapy with an aromatase inhibitor.

III. EXCLUSION CRITERIA

1. Disease progression while receiving Piqray (alpelisib) and fulvestrant combination therapy.
2. Concurrent use with other anti-cancer therapy other than fulvestrant.
3. Dosing exceeds single dose limit of Piqray (alpelisib) 300 mg.
4. Treatment exceeds the maximum limit of 60 (150 mg) tablets/month.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

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. Piqray PI prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey 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.