

Piqray[®] (alpelisib) (Oral)

Document Number: IC-0480

Last Review Date: 07/01/2019

Date of Origin: 07/01/2019

Dates Reviewed: 07/2019

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 300 mg daily dose (28-day supply): Each carton contains 2 blister packs. Each blister pack contains a 14-day supply of 28 tablets (28 tablets, 150 mg alpelisib per tablet)
- 250 mg daily dose (28-day supply): Each carton contains 2 blister packs. Each blister pack contains a 14-day supply of 28 tablets (14 tablets, 200 mg alpelisib per tablet and 14 tablets, 50 mg alpelisib per tablet)
- 200 mg daily dose (28-day supply): Each carton contains 1 blister pack. Each blister pack contains a 28-day supply of 28 tablets (28 tablets, 200 mg alpelisib per tablet)

B. Max Units (per dose and over time) [Medical Benefit]:

- 300 mg per day

III. Initial Approval Criteria

Coverage for drug is provided in the following conditions:

- Patient is at least 18 years or older; **AND**
- Patient has not received prior therapies with other PI3K inhibitors (e.g., idelalisib, duvelisib, copanlisib, etc.); **AND**
- Patient has not received prior therapy with a mammalian target of rapamycin (mTOR) inhibitor (e.g., everolimus, etc.); **AND**
- Patient has the presence of one or more PIK3CA-mutations in tumor tissue or plasma specimens, as detected by an FDA-approved test*; **AND**
- Patient is male or a post-menopausal female; **AND**
- Patient does NOT have inflammatory breast cancer; **AND**

- Patient has a baseline fasting plasma glucose, HbA1c, and does not have diabetes mellitus Type 1 or uncontrolled Type 2; **AND**
- Patient does not have a history of acute pancreatitis within 1 year of therapy or a past medical history of chronic pancreatitis; **AND**

Breast Cancer †

- Patient has advanced or metastatic breast cancer; **AND**
- Patient has progression on or after endocrine-based therapy (e.g., letrozole, anastrozole, exemestane, etc.) OR has relapsed disease within 12 months after completion of adjuvant endocrine therapy; **AND**
- Patient’s cancer is human epidermal growth factor receptor 2 (HER2)-negative; **AND**
- Disease is hormone receptor (HR)-positive; **AND**
- Patient has not received chemotherapy for advanced breast cancer; **AND**
- Patient has not previously been treated with fulvestrant; **AND**
- Treatment will be used in combination with fulvestrant therapy

**<http://www.fda.gov/companiondiagnostics>*

† FDA Approved Indication(s)

IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity, severe cutaneous reactions (\geq Grade 3 rash), severe hyperglycemia (>250 mg/dL), severe pneumonitis/interstitial-lung-disease, severe diarrhea (\geq Grade 2), severe pancreatitis (\geq Grade 2), etc.

V. Dosage/Administration

Indication	Dose
Breast Cancer	The recommended dose is 300 mg (two 150 mg film-coated tablets) taken orally, once daily, with food. Continue treatment until disease progression or unacceptable toxicity occurs. <i>Note: When given with Piqray, the recommended dose of fulvestrant is 500 mg administered on Days 1, 15, and 29, and once monthly thereafter.</i>

VI. Billing Code/Availability Information

HCPCS:

J8999 – Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

NDC:

- 300 mg daily dose: Each carton contains 2 blister packs. Each blister pack contains a 14-day supply of 28 tablets (28 tablets, 150 mg alpelisib per tablet): 00078-0708-xx
- 250 mg daily dose: Each carton contains 2 blister packs. Each blister pack contains a 14-day supply of 28 tablets (14 tablets, 200 mg alpelisib per tablet and 14 tablets, 50 mg alpelisib per tablet): 00078-0715-xx
- 200 mg daily dose: Each carton contains 1 blister pack. Each blister pack contains a 28-day supply of 28 tablets (28 tablets, 200 mg alpelisib per tablet): 00078-0701-xx

VII. References

1. Piqray [package insert]. East Hanover, NJ; Novartis Pharmaceuticals, Corp.; May 2019. Accessed June 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) alpelisib. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2019.
3. André F, Ciruelos E, Rubovszky G, et al. for the SOLAR-1 Study Group. Alpelisib for PIK3CA-Mutated, Hormone Receptor-Positive Advanced Breast Cancer. N Engl J Med. 2019 May 16;380(20):1929-1940. doi: 10.1056/NEJMoa1813904..

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast

ICD-10	ICD-10 Description
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of right male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast

ICD-10	ICD-10 Description
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
Z85.3	Personal history of malignant neoplasm of breast

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC