Alunbrig® (brigatinib)
(Oral)

Document Number: IC-0302

Last Review Date: 05/01/2020
Date of Origin: 5/30/2016
Dates Reviewed: 05/2017, 04/2018, 05/2019, 05/2020

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Alunbrig 30 mg tablets: 2 per day
- Alunbrig 90 mg tablets: 2 per day
- Alunbrig 180 mg tablets: 1 per day
- Alunbrig initiation pack 90 mg/180 mg tablets: 1 per 30 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 180 mg per day

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**

Universal Criteria [1,2]

- Must be used as a single agent; **AND**

Non-Small Cell Lung Cancer (NSCLC) [1-4] † Φ

- Patient has advanced, metastatic or recurrent disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Patient's disease is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved or CLIA compliant test❖; **AND**
    - Used as first-line therapy; **OR**
    - Used as subsequent therapy; **AND**
        - Patient has previously failed with, or is intolerant to, treatment with crizotinib; **OR**
        - Used as continuation of therapy if used first-line, except in cases of symptomatic systemic disease with multiple lesions

Central Nervous System Cancers – Brain Metastases [2] ‡

- Patient has brain metastases from ALK-positive Non-Small Cell Lung Cancer; **AND**
  - Used as initial treatment of with small, asymptomatic brain lesions; **OR**
  - Used for relapsed disease in patients with limited brain metastases and stable systemic disease or reasonable systemic treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

❖ *If confirmed using an immunotherapy assay-http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the universal and indication specific criteria as 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 hypertension, bradycardia, interstitial lung disease/pneumonitis, visual disturbances, creatine phosphokinase (CPK) elevation, pancreatic enzyme elevation, severe hyperglycemia, etc.

V. Dosage/Administration

Indication	Dose
NSCLC, CNS Cancer	Administer 90 mg orally once daily for the first 7 days and, if tolerated, increase to 180 mg once daily. Administer until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS code:

- J8999: Prescription drug, oral, chemotherapeutic, nos

NDC:

- Alunbrig 30 mg tablet: 63020-0113-xx
- Alunbrig 90 mg tablet: 63020-0090-xx
- Alunbrig 180 mg tablet: 63020-0180-xx
- Alunbrig 90 mg tablet/7 count tablets and 180 mg tablet/23 count tablets one-month initiation pack: 63020-0198-xx

VII. References

1. Alunbrig [package insert]. Cambridge, MA; Ariad Pharmaceuticals, Inc., December 2018. Accessed April 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for brigatinib. National Comprehensive Cancer Network, 2020. 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 April 2020.
3. Camidge DR, Bazhenova L, Salgia R, et al. Safety and efficacy of brigatinib (AP26113) in advanced malignancies, including ALK+ non–small cell lung cancer (NSCLC). Journal of Clinical Oncology33, no. 15_suppl(May 20, 2015)8062-8062.
4. Ou SHI, Tiseo M, Camidge DR, et al. Brigatinib (BRG) in patients (pts) with crizotinib (CRZ)-refractory ALK+ non-small cell lung cancer (NSCLC) and brain metastases in the pivotal randomized phase 2 ALTA trial. Journal of Clinical Oncology 2017 35:15_suppl, e20502-e20502
5. Camidge DR, Kim DW, Tiseo M, et al. Exploratory Analysis of Brigatinib Activity in Patients With Anaplastic Lymphoma Kinase-Positive Non-Small-Cell Lung Cancer and Brain Metastases in Two Clinical Trials. Clin Oncol. 2018 Sep 10;36(26):2693-2701. doi: 10.1200/JCO.2017.77.5841. Epub 2018 May 16.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C79.31	Secondary malignant neoplasm of brain

ICD-10	ICD-10 Description
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

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), Local Coverage Determinations (LCDs), and Local Coverage Article (LCAs) 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/LCA): 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