PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Alunbrig Prior Authorization Policy
- Alunbrig® (brigatinib tablets – ARIAD/Takeda)

REVIEW DATE: 07/12/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Alunbrig, a kinase inhibitor, is indicated for the treatment of adults with anaplastic lymphoma kinase (ALK)-positive, metastatic **non-small cell lung cancer (NSCLC)** as detected by an FDA-approved test.[1]

Guidelines

Alunbrig is addressed in National Comprehensive Cancer Network (NCCN) guidelines:[2-5]

- **Histiocytic Neoplasms:** Guidelines (version 1.2022 – May 20, 2022) recommend Alunbrig as a "useful in certain circumstances" treatment option for *ALK*-positive Erdheim-Chester disease (category 2A).[3]
- **Inflammatory Myofibroblastic Tumor (IMT):** NCCN Soft Tissue Sarcoma guidelines (version 2.2023 – April 25, 2023) and NCCN Uterine Neoplasms guidelines (version 2.2023 – April 28, 2023) recommend Alunbrig as a treatment option for IMT with *ALK* translocation.[5,6]
- **NSCLC:** Guidelines (version 3.2023 – April 13, 2023) recommend testing for *ALK* rearrangements in eligible patients with NSCLC.[4] If *ALK* rearrangement is discovered prior to first-line systemic therapy, Alunbrig is a preferred first-line treatment option (category 1). If *ALK* rearrangement is discovered during first-line systemic therapy, options are to complete the planned systemic therapy (including maintenance therapy) or to interrupt the systemic therapy

and treat with Alunbrig ("preferred", category 2A) or another ALK inhibitor. NCCN recommendations for patients with disease progression often include continuing the first-line targeted therapy, depending on type of progression.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Alunbrig. All approvals are provided for the duration noted below.

- **Alunbrig® (brigatinib tablets (ARIAD/Takeda)**

is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patients meets the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has advanced or metastatic disease; AND
   C) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
   D) The mutation was detected by an approved test.

Other Uses with Supportive Evidence

2. **Erdheim-Chester Disease.** Approve for 1 year if the patient meets the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has anaplastic lymphoma kinase (*ALK*) rearrangement/fusion-positive disease.

3. **Inflammatory Myofibroblastic Tumor.** Approve for 1 year if the patients meets the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease;
   C) Patient meets one of the following (i or ii):
      i. Patient has advanced, recurrent, or metastatic disease; OR
      ii. The tumor is inoperable.

CONDITIONS NOT COVERED

- **Alunbrig® (brigatinib tablets (ARIAD/Takeda)**

is(are) considered experimental, investigational or unproven for ANY other use(s).

REFERENCES

1. Alunbrig® tablets [prescribing information]. Cambridge, MA: ARIAD/Takeda; February 2022.
2. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 3, 2023. Search terms: brigatinib.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2022 – May 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 3, 2023.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – April 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 3, 2023.
5. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2023 – April 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 3, 2023.
6. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2023 – April 28, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 3, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Erdheim-Chester Disease:** This new condition of approval was added to the policy. **Inflammatory Myofibroblastic Tumor:** The condition name was changed to as listed; previously, the approval condition was titled Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT). **Non-Small Cell Lung Cancer:** Added criterion that disease is advanced or metastatic; previously, the criterion read: Patient has metastatic non-small cell lung cancer.	07/13/2022
Selected Revision	**Inflammatory Myofibroblastic Tumor:** The requirement that the disease is advanced, recurrent, or metastatic or the tumor is inoperable was added.	01/11/2023
Annual Revision	No criteria changes	07/12/2023