PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/07/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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 anaplastic lymphoma kinase (ALK)-positive, metastatic **non-small cell lung cancer (NSCLC)** in adults, 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 2.2024 – July 19, 2024) 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 2.2024 – July 31, 2024) recommend Alunbrig as a "Preferred" treatment option for IMT with *ALK* translocation (category 2A). The NCCN Uterine Neoplasms guidelines (version 2.2024 – March 6, 2024) recommend Alunbrig as "Useful in Certain Circumstances" for first-line therapy for advanced, recurrent/metastatic, or inoperable IMT with ALK translocation for uterine sarcoma (category 2A).[5,6]
- **NSCLC:** Guidelines (version 7.2024 – July 26, 2024) 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.

- **T-Cell Lymphomas:** Guidelines (version 4.2024 – May 28, 2024) recommend Alunbrig for ALK-positive anaplastic large-cell lymphoma (ALCL) under "other recommended regimens" (category 2A) for initial palliative-intent therapy and for second-line/subsequent therapy (regardless of intention to transplant).

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 ALL of 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 BOTH of 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 ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
   C) Patient meets ONE of the following (i or ii):
      i. Patient has advanced, recurrent, or metastatic disease; OR
      ii. The tumor is inoperable.

4. **Peripheral T-Cell Lymphomas.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has anaplastic lymphoma kinase (ALK)-positive anaplastic large cell lymphoma (ALCL).

CONDITIONS NOT COVERED

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

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following; criteria will be updated as new published data are available.

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 August 1, 2024. Search terms: brigatinib.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – July 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 1, 2024.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 7.2024 – June 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 1, 2024.
5. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2024 – July 31, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 1, 2024.
6. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – March 6, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 1, 2024.
7. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2024 – May 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 1, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	07/12/2023
Annual Revision	**Peripheral T-Cell Lymphomas:** Added new approval condition and criterion under "Other Uses with Supportive Evidence".	08/07/2024