PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Alecensa Prior Authorization Policy
- Alecensa® (alectinib capsules – Genentech)

REVIEW DATE: 02/05/2025

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

Alecensa, a tyrosine kinase inhibitor, is indicated for **Non-Small Cell Lung Cancer (NSCLC)** for the following in adults:[1]
- Adjuvant treatment following tumor resection of *ALK*-positive NSCLC (tumors ≥ 4 cm or node positive), as detected by an FDA-approved test.
- Treatment of anaplastic lymphoma kinase (*ALK*)-positive, metastatic disease as detected by an FDA-approved test.[1]

According to the Alecensa prescribing information, for adjuvant treatment of resected NSCLC the therapy duration is for a total of 2 years or until disease recurrence or unacceptable toxicity.[1]

GUIDELINES

Alecensa has been addressed in National Comprehensive Cancer Network (NCCN) guidelines:[2]
- **B-Cell Lymphomas:** Guidelines (version 1.2025 – December 20, 2024) recommend Alecensa (category 2A) for relapsed or refractory *ALK*-positive large B-cell lymphomas.[7]
- **Histiocytic Neoplasms:** Guidelines (version 3.2024 – January 7, 2025) recommend Alecensa as a "useful in certain circumstances" treatment option for *ALK*-positive Erdheim-Chester Disease (category 2A).[3]

- **Non-Small Cell Lung Cancer:** Guidelines (version 3.2025 – January 14, 2025) recommend testing for *ALK* rearrangements in eligible patients with NSCLC.[4] Alecensa is recommended for 24 months in patients with NSCLC, positive for *ALK* rearrangement (category 1). If *ALK* rearrangement is discovered prior to first-line systemic therapy for advanced or metastatic disease, Alecensa is a "Preferred" first-line treatment option (category 1). If *ALK* rearrangement is discovered during first-line systemic therapy, NCCN recommends interrupting the systemic therapy and treat with Alecensa ("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.
- **Pediatric Central Nervous System Cancers:** Guidelines (version 2.2025 – January 17, 2025) recommend Alecensa for *ALK*-positive disease in adjuvant setting (category 2A) and for recurrent or progressive pediatric diffuse high-grade gliomas.[8] The guideline refers to children and adolescents ≤ 21 years of age. The Compendium notes that for adjuvant treatment it cannot be used for diffuse midline glioma, H3 K27-altered or pontine location.[2]
- **T-Cell Lymphomas:** Guidelines (version 1.2025 – November 11, 2024) recommend Alecensa as a treatment option for initial palliative-intent therapy in *ALK*-positive disease or for patients with relapsed or refractory *ALK*-positive anaplastic large cell lymphoma (ALCL).[5] NCCN notes a phase II study involving patients ≥ 6 years of age with relapsed or refractory *ALK*-positive ALCL. However, this was a small study involving 10 patients with a median age of 19.5 years.
- **Uterine Neoplasms:** Guidelines (version 2.2025 – January 31, 2025) recommend Alecensa as a treatment option for patients with inflammatory myofibroblastic tumor with *ALK* translocation (category 2A).[6]

POLICY STATEMENT

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

- **Alecensa® (alectinib capsules (Genentech))**

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 – Advanced or Metastatic Disease.** Approve for 1 year if the patient 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) The mutation was detected by an approved test.

2. **Non-Small Cell Lung Cancer – Adjuvant Therapy.** Approve for a total of 2 years if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
   C) The medication is used following tumor resection (tumors ≥ 4 cm or node positive); AND
   D) The mutation was detected by an approved test.

Other Uses with Supportive Evidence

3. **Anaplastic Large Cell Lymphoma.** Approve for 1 year if the patient 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. The medication is used for palliative-intent therapy; OR
      ii. Patient has relapsed or refractory disease.

4. **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.

5. **Inflammatory Myofibroblastic Tumor.** Approve for 1 year if the patient 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.

6. **Large B-Cell Lymphoma.** Approve for 1 year if the patient 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 has relapsed or refractory disease.

7. **Pediatric Diffuse High-Grade Gliomas.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   A) Patient is ≤ 21 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 meets BOTH of the following (a and b):
         a) The medication is used for adjuvant treatment; AND
         b) The tumor is not diffuse midline glioma, H3 K27-altered or pontine location; OR
      ii. The medication is used for recurrent or progressive disease.

CONDITIONS NOT COVERED

- **Alecensa® (alectinib capsules (Genentech))**

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

REFERENCES

1. Alecensa® capsules [prescribing information]. South San Francisco, CA: Genentech; April 2024.

2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 31, 2025. Search term: alectinib.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 3.2024 – January 7, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 31, 2025.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – January 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 31, 2025.
5. The NCCN T-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 1.2025 – November 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 31, 2025.
6. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2025 – January 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 31, 2025.
7. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 1.2025 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 31, 2025.
8. The NCCN Pediatric Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 2.2025 – January 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 31, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	**Inflammatory Myofibroblastic Tumor:** This new condition of approval was added to the policy	01/11/2023
Annual Revision	**Anaplastic Large Cell Lymphoma:** Added criterion that the medication can be used for palliative-intent therapy based on guideline recommendations. **Large B-Cell Lymphoma:** This condition and criteria for approval was added to the policy under "Other Uses with Supportive Evidence."	01/17/2024
Selected Revision	**Non-Small Cell Lung Cancer:** Added criterion for adjuvant treatment after tumor resection based on new indication approval**.**	05/08/2024
Annual Revision	**Non-Small Cell Lung Cancer – Advanced or Metastatic Disease:** Added qualifier "Advanced or Metastatic Disease." Deleted adjuvant therapy criteria from this indication since it is addressed separately. Deleted criteria requiring advanced or metastatic disease since it is now addressed in the indication. **Non-Small Cell Lung Cancer – Adjuvant Therapy:** Separated "Adjuvant Therapy" indication from advanced or metastatic disease criteria. The approval duration has been updated to a "total of 2 years", based on the prescribing information. **Pediatric Diffuse High Grade Glioma:** Added new approval condition and criteria under "Other Uses with Supportive Evidence" based on guideline recommendations.	02/05/2025