

# Lorbrena (lorlatinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Lorbrena (lorlatinib)	May be subject to quantity limit

## APPROVAL CRITERIA

Requests for Lorbrena (lorlatinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of anaplastic lymphoma kinase (ALK) - positive recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC) (Label, NCCN 1, 2A); **AND**
- II. Individual is using as a single agent;

**OR**

- III. Individual has a diagnosis of recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC) with ROS 1-positive tumors (Label, NCCN 2A); **AND**
- IV. Individual's disease has progressed on either, ceritinib, crizotinib, or entrectinib; **AND**
- V. Individual is using as a single agent;

**OR**

- VI. Individual has a diagnosis of ALK rearrangement-positive non-small cell lung cancer with limited or extensive brain metastases (NCCN 2A); **AND**
- VII. Individual has a primary diagnosis of ALK-positive NSCLC; **AND**
- VIII. Individual is using as a single treatment for recurrent disease with stable systemic disease or reasonable systemic treatment options;

**OR**

- IX. Individual has a diagnosis of Soft Tissue Sarcoma (NCCN 2A); **AND**
- X. Individual is using as monotherapy for Inflammatory Myofibroblastic Tumor (IMT) with ALK translocation;

**OR**

- XI. Individual has a diagnosis of ALK rearrangement-positive Diffuse large B-cell lymphoma (NCCN 2A); **AND**
- XII. Individual is using for relapsed or refractory disease;

**OR**

- XIII. Individual has advanced, recurrent/metastatic, or inoperable uterine sarcoma (NCCN 2A); **AND**
- XIV. Individual is using as monotherapy for IMT with ALK translocation;

**OR**

- XV. Individual has a diagnosis of Erdheim-Chester Disease (ECD) (NCCN 2A); **AND**
- XVI. Individual has relapsed/refractory disease or ECD with symptomatic disease; **AND**
- XVII. Individual has an ALK positive mutation; **AND**
- XVIII. Individual is using as a single agent.

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 1, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Kemps PG, Picarsic J, Durham BH, et al. ALK-positive histiocytosis: a new clinicopathologic spectrum highlighting neurologic involvement and responses to ALK inhibition. *Blood*. 2022;139(2):256-280. doi:10.1182/blood.2021013338 Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8759533/>. Accessed July 1, 2023
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 1, 2023
  - a. B-Cell Lymphomas. V4.2023. Revised June 2, 2023.
  - b. Central Nervous system Cancers. V1.2023. Revised March 24, 2023.
  - c. Histiocytic Neoplasms. V1.2022. Revised May 20, 2022.
  - d. Non-Small Cell Lung Cancer. V3.2023 Revised April 13, 2023.
  - e. Soft Tissue Sarcoma. V2.2023. Revised April 25, 2023.
  - f. Uterine Neoplasms. V2.2023. Revised April 28, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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