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 a diagnosis of relapsed/refractory anaplastic large cell lymphoma (ALCL) (NCCN 2A); **AND**

XIV. Individual has ALK positive disease; **AND**
XV. Individual is using as a single agent;

OR

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

OR

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

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. 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: June 21, 2024.
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 June 21, 2024.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. . Accessed on June 27, 2024.
    a. B-Cell Lymphomas. V2.2024. Revised April 30, 2024.
    b. Central Nervous system Cancers. V1.2024. Revised May 31, 2024.
    c. Histiocytic Neoplasms. V1.2024. Revised March 15, 2024.
    d. Non-Small Cell Lung Cancer. V7.2024 Revised June 26, 2024.
    e. Soft Tissue Sarcoma. V1.2024. Revised April 26, 2024.
    f. T-cell Lymphoma. V4.2024. Revised May 28, 2024.
    g. Uterine Neoplasms. V2.2024. Revised March 6, 2024.