Reference number(s)
2787-A

Specialty Guideline Management
Lorbrena

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lorbrena	lorlatinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Lorbrena is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

Compendial Uses[2]

- Single-agent therapy for recurrent, advanced or metastatic NSCLC in patients with:
  - ALK rearrangement-positive tumors
  - ROS1 rearrangement-positive tumors, following disease progression
- Inflammatory myofibroblastic tumor (IMT) with ALK translocation
  - Uterine sarcoma
  - Soft tissue sarcoma
- Erdheim-Chester disease with ALK fusion
- ALK-positive large B-cell lymphoma

- Pediatric diffuse high-grade glioma
- ALK-positive anaplastic large cell lymphoma (ALCL)

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: Chart documentation indicating ALK mutation status or ROS1 rearrangement status (where applicable).

Coverage Criteria

Non-Small Cell Lung Cancer (NSCLC)[1,2]

Authorization of 12 months may be granted for treatment of ALK rearrangement-positive recurrent, advanced, or metastatic NSCLC (including brain metastases from NSCLC) as a single-agent.

Authorization of 12 months may be granted for treatment of recurrent, advanced, or metastatic NSCLC as a single-agent therapy when all of the following criteria are met:

- The disease is ROS1 rearrangement-positive
- The disease has progressed on any of the following: crizotinib, entrectinib repotrectinib, or taletrectinib

Inflammatory Myofibroblastic Tumor (IMT)[2]

Authorization of 12 months may be granted for treatment of ALK-positive IMT as a single agent when either of the following criteria is met:

- The member has uterine sarcoma and the disease is advanced, recurrent, metastatic, or inoperable
- The member has a soft tissue sarcoma (not including uterine sarcoma)

Erdheim-Chester Disease[2]

Authorization of 12 months may be granted for treatment of ALK-positive Erdheim-Chester disease as a single agent.

Diffuse Large B-Cell Lymphoma[2]

Authorization of 12 months may be granted for treatment of relapsed or refractory ALK-positive large B-cell lymphoma.

Pediatric Diffuse High-Grade Glioma[2]

Authorization of 12 months may be granted for treatment of ALK-rearrangement positive pediatric diffuse high-grade glioma when either of the following criteria is met:

- The disease is recurrent or progressive and the member does not have IDH-mutant and 1p/19q co-deleted oligodendroglioma or IDH-mutant astrocytoma.
- The request is for adjuvant treatment and the member does not have disease that is diffuse midline, H3 K27-altered or pontine location.

Anaplastic Large Cell Lymphoma (ALCL)[2]

Authorization of 12 months may be granted for treatment of relapsed/refractory ALK-positive ALCL as a single agent.

Continuation of Therapy

Non-Small Cell Lung Cancer (NSCLC)[1,2]

Authorization of 12 months may be granted for continued treatment of non-small cell lung cancer (NSCLC) in members requesting reauthorization when there is no evidence of unacceptable toxicity while on the current regimen.

All Other Indications[2]

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Lorbrena [package insert]. New York, NY: Pfizer, Inc.; August 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed July 14, 2025.