

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

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 2A); **AND**
 - A. Individual's disease has progressed on crizotinib and at least one other ALK inhibitor therapy, except in cases of isolated lesions; **OR**
 - B. Individual's disease has progressed on crizotinib and subsequent therapy with crizotinib for asymptomatic disease or isolated lesions; **OR**
 - C. Individual's disease has progressed on alectinib, brigatinib, or ceritinib as first ALK inhibitor therapy for multiple lesions; **OR**
 - D. Individual's disease has progressed on alectinib, brigatinib, or ceritinib and subsequent therapy with alectinib, brigatinib, or ceritinib except in cases of multiple lesions;

OR

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

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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 20, 2020
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 20, 2020.

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New Program Date 01/15/2019

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- a. Non-Small Cell Lung Cancer. V6.2020. Revised June 15, 2020.

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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