I. Medication Description

Lorlatinib is a kinase inhibitor with in vitro activity against anaplastic lymphoma kinase (ALK) and ROS1 as well as TYK1, FER, FPS, TRKA, TRKB, TRKC, FAK, FAK2, and ACK. Lorlatinib demonstrated in vitro activity against multiple mutant forms of the ALK enzyme, including some mutations detected in tumors at the time of disease progression on crizotinib and other ALK inhibitors. The overall antitumor activity of Lorlatinib in in vivo models was dose-dependent and correlated with inhibition of ALK phosphorylation.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

- Member is at least 18 years old AND
- The medication is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is available as follows:
- 100 mg tablets: up to 30 tablets per 30 days
- 25 mg tablets: up to 90 tablets per 30 days

V. Coverage Duration

Coverage is available for 6 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:
- Stabilization of disease or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug
<table>
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<tr>
<th>Drug Therapy Guidelines</th>
<th>Lorbrena® (lorlatinib)</th>
<th>Last Review Date: 9/2019</th>
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### VII. Billing/Coding Information

Lorbrena is available as 25 mg and 100 mg tablets

### VIII. Summary of Policy Changes

- 2/15/19: new policy
- 11/15/19: no policy changes

### IX. References


*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.*

*The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.*

*The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*