Lorbrena (lorlatinib)
Effective 01/01/2021

Plan | ☐ MassHealth
     | ☑ MassHealth (PUF)
     | ☐ Commercial/Exchange
Program Type | ☑ Prior Authorization
             | ☐ Quantity Limit
             | ☐ Step Therapy

Benefit | ☑ Pharmacy Benefit
         | ☐ Medical Benefit (NLX)

Specialty Limitations | This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

Contact Information

<table>
<thead>
<tr>
<th>Specialty Medications</th>
<th>All Plans</th>
<th>Phone: 866-814-5506</th>
<th>Fax: 866-249-6155</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-Specialty Medications</td>
<td>MassHealth</td>
<td>Phone: 877-433-7643</td>
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<tr>
<td></td>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
<td>Fax: 888-836-0730</td>
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<td></td>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
</tr>
<tr>
<td>Medical Specialty Medications (NLX)</td>
<td>All Plans</td>
<td>Phone: 844-345-2803</td>
<td>Fax: 844-851-0882</td>
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</tbody>
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Exceptions | N/A

Overview
Lorlatinib is a reversible potent third generation tyrosine kinase inhibitor that targets ALK and ROS1; it is highly selective, overcomes known ALK resistance mutations, and penetrates the blood brain barrier (Shaw 2017). Lorlatinib has antitumor 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. Antitumor activity of lorlatinib is dose-dependent and correlates with inhibition of ALK phosphorylation. Lorlatinib also exhibits activity against TYK1, FER, FPS, TRKA, TRKB, TRKC, FAK, FAK2, and ACK.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Lorbrena, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs
OR
Authorization of may be granted when ALL of the following criteria are met and documentation is submitted:
1. The member has a diagnosis of advanced or metastatic non-small cell lung cancer (NSCLC)
2. Prescriber is an oncologist
3. Appropriate dosing
4. Cancer is ALK-positive (Documentation must be provided on the PA request or in attached medical records)
5. ONE of the following:
a. Provider documentation of inadequate response or adverse reaction to Xalkori® (crizotinib) and at least one other ALK inhibitor† (History of claims is not sufficient)

b. Provider documentation of inadequate response or adverse reaction to Alecensa® (alectinib) or Zykadia® (ceritinib) (History of claims is not sufficient)

6. Quantity requested is ≤1 unit/day

†ALK inhibitors include: Alecensa® (alectinib), Alunbrig® (brigatinib), Zykadia® (ceritinib).

Continuation of Therapy
Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.

Limitations
1. Approvals will be granted for 3 months.
2. Reauthorization will be granted for 6 months.
3. The following quantity limits apply:

| Lorbrena | 30 tablets per 30 days |

References
2. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.;

Review History
11/20/19 – Reviewed at P&T
10/6/20 – Updated to be in compliance with the MassHealth partial unified formulary requirements; split from COMM criteria.

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.