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| Reference number(s) |
| 2787-A              |

## SPECIALTY GUIDELINE MANAGEMENT

### LORBRENA (lorlatinib)

#### POLICY

##### I. 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 Indication

Lorbrena is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on:

- Crizotinib and at least one other ALK inhibitor for metastatic disease; or
- Alectinib as the first ALK inhibitor therapy for metastatic disease; or
- Ceritinib as the first ALK inhibitor therapy for metastatic disease

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

##### **Non-small cell lung cancer (NSCLC)**

Authorization of 12 months may be granted for treatment of metastatic NSCLC when all of the following criteria are met:

- A. The disease is anaplastic lymphoma kinase (ALK)-positive
- B. The disease has progressed on any of the following therapies for metastatic disease:
  1. Crizotinib and at least one other ALK inhibitor
  2. Alectinib as the first ALK inhibitor therapy
  3. Ceritinib as the first ALK inhibitor therapy

##### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

##### IV. REFERENCE

1. Lorbrena [package insert]. New York, NY: Pfizer, Inc.; November 2018.