Commercial/Healthcare Exchange PA Criteria

Effective: January 13, 2016

Prior Authorization: Alecensa

Products Affected: Alecensa (alectinib) oral capsule

Medication Description:
Certain patients with non-small cell lung cancer (NSCLC) have tumors that contain an inversion in chromosome 2 that juxtaposes the 5' end of the echinoderm microtubule-associated protein-like 4 (EML4) gene with the 3' end of the anaplastic lymphoma kinase (ALK) gene, resulting in the novel fusion oncogene EML4-ALK. This fusion oncogene rearrangement is transforming both in vitro and in vivo and defines a distinct clinicopathologic subset of NSCLC. Tumors that contain the EML4-ALK fusion oncogene or its variants are associated with specific clinical features, including never or light smoking history, younger age, and adenocarcinoma with signet ring or acinar histology. ALK gene arrangements are largely mutually exclusive with epidermal growth factor receptor (EGFR) or KRAS mutations. Screening for this fusion gene in NSCLC is important, as "ALK-positive" tumors (tumors harboring a rearranged ALK gene/fusion protein) are highly sensitive to therapy with ALK-targeted inhibitors.

In certain NSCLC populations, the ALK rearrangement is a relatively rare event. In the initial report, 5 of 75 lung tumors (7 percent) demonstrated expression of the fusion transcript. The overall incidence of ALK gene rearrangements in subsequent series has been about 4 percent. Except in rare cases, the presence of ALK gene rearrangements in NSCLC tumors tends to occur independent of epidermal growth factor receptor (EGFR) or KRAS mutations. Similar frequencies of ALK gene rearrangements have been reported in Asian and Western populations.

While the overall frequency of ALK fusion oncogene in the general NSCLC population is low, knowledge of the clinicopathologic features enables enrichment for this genetically defined subset. In one study in which patients were selected for genetic screening based on clinical features commonly associated with EGFR mutation, including never/light smoking status and adenocarcinoma histology, 13 percent harbored the ALK fusion oncogene. Within the group of never or light smokers in this study, the frequency of ALK positivity was 22 percent, and among never or light smokers who did not have an EGFR mutation, the frequency was 33 percent . These findings suggest that in NSCLC patients with clinical characteristics associated with EGFR mutation but with negative EGFR testing, as many as one in three may harbor the ALK fusion oncogene.

Two tyrosine kinase (TK) inhibitors, crizotinib and ceritinib, have established roles in the treatment of anaplastic lymphoma kinase (ALK) fusion oncogene positive NSCLC, and additional agents are under development. While crizotinib is highly active in patients with ALK-positive NSCLC, almost all patients develop resistance to the drug, typically within the first few years of treatment. Alectinib is another second generation ALK inhibitor that has activity in crizotinib resistant disease with reported activity in brain metastases.

Covered Uses:

1. Anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test

Exclusion Criteria: N/A

Required Medical Information:

1. Confirmed ALK-positive NSCLC as detected by an FDA-approved test

Age Restrictions: 18 years or older

Prescriber Restrictions: Prescribed by, or in consultation with, an Oncologist

Coverage Duration: 3 years

Other Criteria:

Anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC)

A. The patient has metastatic ALK-positive NSCLC as detected by an FDA-approved test.

References:

1. Alecensa. [package insert]. San Francisco, CA: Genentech Inc.; November 2015.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 2.2016). © 2015 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on November 24, 2015.
3. Shaw AT et al. Anaplastic lymphoma kinase (ALK) fusion oncogene positive non-small cell lung cancer. In: UpToDate, Jett JR (Ed), UpToDate, Waltham, MA. (Accessed on December 21, 2015.)

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	Adopted EH policy EH policy revision history: 1/2016, 10/2018, 7/2019, 6/2020	All	01/13/2016
2	Update	Removal of "other criteria": The patient has progressed on or is intolerant to Xalkori (crizotinib) Removal of "required medical information: Previous therapies tried/failed	Other criteria Required Medical information	6/17/2020