ALECTINIB

Generic	Brand	HICL	GCN	Exception/Other
ALECTINIB	ALECENSA	42895		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
   - Patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene as detected by an FDA-approved test

     If yes, **approve for 12 months by HICL with a quantity limit of #240 capsules per 30 days.**
     If no, do not approve.
     DENIAL TEXT: The guideline named **ALECTINIB (Alecensa)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC) AND patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene as detected by an FDA-approved test.

RATIONALE
Promote appropriate utilization of ALECTINIB based on its FDA approved indication.

FDA APPROVED INDICATIONS
Alecensa is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION
The recommended dose of Alecensa is 600 mg orally twice daily with food. Alecensa therapy is continued until disease progression or unacceptable toxicity.

The dose of Alecensa can be modified if certain adverse reactions or laboratory abnormalities occur (e.g., elevated hepatic transaminases, bradycardia, elevated CPK). The dose should be reduced first to 450 mg twice daily, then to 300 mg twice daily, and discontinued if intolerability persists thereafter. If treatment-related ILD/pneumonitis, elevated ALT or AST greater than 3 times ULN with total bilirubin greater than 2 times ULN in the absence of cholestasis or hemolysis, grade 4 renal impairment, or life-threatening bradycardia occurs, Alecensa should be permanently discontinued.

The contents of the capsule should not be opened or dissolved. If a dose is missed or vomiting occurs after taking a dose, the next dose should be taken at the scheduled time.

REFERENCES
- Alecensa [Prescribing Information]. South San Francisco, CA: Genentech, Inc. November 2017.

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Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/18

Created: 12/15
Client Approval: 12/17

P&T Approval: 01/18