BRIGATINIB

Generic	Brand	HICL	GCN	Exception/Other
BRIGATINIB	ALUNBRIG	44226		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet ALL of the following criteria?
   - The patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene
   - The patient has progressed or is intolerant to Xalkori (crizotinib)

   If yes, **approve for 12 months by GPID with the following quantity limits:**
   - **Alunbrig 30mg (GPID 43325): #120 tablets per 30 days.**
   - **Alunbrig 90mg (GPID 43326): #30 tablets per 30 days.**
   - **Alunbrig 180mg (GPID 44305): #30 tablets per 30 days.**
   - **Alunbrig initiation pack (GPID 44306): #30 tablets per 30 days.**

   If no, do not approve.
   DENIAL TEXT: The guideline named **BRIGATINIB (Alunbrig)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC). In addition, the following criteria must be met:
   - The patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene
   - The patient has progressed or is intolerant to Xalkori (crizotinib)

RATIONALE

Promote appropriate utilization of **BRIGATINIB** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS

Alunbrig is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. 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.

DOSAGE AND ADMINISTRATION

The recommended dose of Alunbrig as treatment is 90 mg orally once daily for the first 7 days; if tolerated, increase to 180 mg orally once daily. May be taken with or without food.

Administer Alunbrig until disease progression or unacceptable toxicity.

If Alunbrig is interrupted for 14 days or longer for reasons other than adverse reactions, resume treatment at 90 mg once daily for 7 days before increasing to the previously tolerated dose.

Alunbrig may be taken with or without food. Instruct patients to swallow tablets whole. Do not crush or chew tablets.

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FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION
If a dose of Alunbrig is missed or vomiting occurs after taking a dose, do not administer an additional dose and take the next dose of Alunbrig at the scheduled time.

To manage adverse reactions, consider interruption of treatment or dose reduction. Recommended dose reductions are summarized in Table 1.

Table 1. Recommended Dose Adjustments

Dose	Dose Reduction Levels		
	First	Second	Third
90 mg once daily	60 mg once daily	Permanently discontinue	N/A
180 mg once daily	120 mg once daily	90 mg once daily	60 mg once daily

Once reduced for adverse reactions, do not subsequently increase the dose of Alunbrig. Permanently discontinue Alunbrig if patients are unable to tolerate the 60 mg once daily dose.

DOSAGE FORMS AND STRENGTHS
Tablets: 180 mg, 90 mg, and 30 mg

REFERENCES

- Alunbrig [Prescribing Information]. Cambridge, MA: Ariad Pharmaceuticals; October 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/18
Created: 07/17
Client Approval: 02/18
P&T Approval: 01/18