ALECENSA Sample Appeal Letter

[Date]

[Payer name]
ATTN: APPEALS
[Payer contact name]
[Payer address]

Patient: [Patient's first and last name]
Subscriber ID#: [Insurance ID #]
Subscriber Group #: [Insurance group #]
Re: ALECENSA® (alectinib) tablets
Date(s) of Service: [Include all denied dates of service]

Dear Appeals Reviewer:

I am writing to request [appeal/redetermination/reconsideration] of the above denial(s) of ALECENSA® (alectinib) tablets for my patient [patient name]. I understand from your denial letter that the denials were based on [denial reason]. I would like to address [that reason/those reasons] now. I would appreciate a prompt review of the enclosed information demonstrating medical necessity and coverage for ALECENSA.

Patient's Clinical History
[Patient name] is a [age] year old [male/female] who was diagnosed on [date] with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer and [has progressed on/is intolerant to] crizotinib. Treatment options are limited for this patient population. [He/She] underwent [describe treatment to date].

- [Include diagnosis and dates]
- [Past treatments]
- [Test results that indicate failure of past treatment]
- [Extenuating circumstances that would preclude alternatives to ALECENSA]
- [Social & family information]

[REMINDER: If a payer has a published policy, include here]
[REMINDER: If state statute exists, include here]

Treatment Rationale
On [date], the FDA approved the use of ALECENSA 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.

The approval came after results of two single arm, multicenter studies which demonstrated improvement in objective response rate and duration of response.

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ALECENSA has shown to be a highly selective and potent ALK and RET tyrosine kinase inhibitor, leading to the blockage of downstream signaling pathways, including STAT 3 and AKT. STAT 3 and AKT are involved in the regulation of cell growth, cell proliferation and cell survival. The blockage of these pathways induces tumor apoptosis.

ALECENSA also demonstrated *in vitro* and *in vivo* activity against mutant forms of the ALK enzyme, including mutations responsible for resistance to crizotinib.

[Include plan of treatment (dosage, length of treatment), FDA Approval Letter, relevant journal articles, clinical studies, and clinical practice guidelines that support the use of ALECENSA. Consider mentioning experts in the field who also support the treatment.3]

Summary
In summary, I am requesting [appeal/redetermination/reconsideration] of the denial of ALECENSA therapy for my patient, [patient name]. My patient was diagnosed with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer and [has progressed on/is intolerant to] crizotinib. I am requesting that you reconsider coverage based on the information above. I am readily available at my office phone [MD phone number] to address any questions or concerns you might have regarding this appeal.

Thank you for your time and consideration.

Sincerely,

(Physician's name and credentials)

Enclosures (suggested enclosures below – delete what is not applicable):

- FDA Approval Letter for ALECENSA
- Package Insert for ALECENSA
- Safety information for ALECENSA (safety information can be found at www.ALECENSA.com)
- Payer denial letter
- Clinical notes/diagnostic pathology report
- CT/PET scans showing progressive disease
- Journal articles, clinical practice guidelines and other supporting documentation.