

April 27, 2015

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NCCN Guidelines Panel: Non-Small Cell Lung Cancer

On behalf of Merck & Co., Inc., I respectfully request the NCCN Panel review the enclosed information for inclusion of Keytruda (pembrolizumab) on the NCCN Treatment Guidelines of Non-Small Cell Lung Cancer.

Specific changes requested:

In section NSCL-F we respectfully request that Keytruda be considered for systemic therapy for patients with stage IV non-small cell lung cancer.

FDA Clearance:

The FDA approved Keytruda (pembrolizumab) for treatment of unresectable or metastatic melanoma in patients who progressed on or after treatment with ipilimumab and, if BRAF V600 mutation positive, received treatment with a BRAF or MEK inhibitor on September 4, 2014.

Rationale:

In an article published in The New England Journal of Medicine, April 19, 2015, Garon et al reported results from a phase 1 study which assessed the efficacy and safety of programmed cell death 1 inhibition with pembrolizumab (2mg/kg or 10 mg/kg every 3 weeks or 10 mg/kg every 2 weeks) in patients with advanced non-small-cell lung cancer; the results showed that pembrolizumab had an acceptable side-effect profile and showed antitumor activity in patients with advanced non-small-cell lung cancer (among all patients, the objective response rate was 19.4%, and the median duration of response was 12.5 months, the median duration of survival was 12.0 months; among patients with a proportion score of a least 50% in the validation group, the response rate was 45.2%).

To assist the committee with their review, I have included the following resources:

1. Keytruda (pembrolizumab) prescribing information. Merck & Co., Inc.
2. Garon et al. Pembrolizumab for the Treatment of Non-Small Cell Lung Cancer. The New England Journal of Medicine. April 19, 2015.



Garon.pdf



KEYTRUDA_pi.pdf

Thank you for considering this request. Below is my contact information should you need to contact me for additional information.

Sincerely,

A handwritten signature in black ink, appearing to read 'Craig Granowitz'.

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