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NCCN Guidelines Panel: Non-Small Cell Lung Cancer

On behalf of Merck & Co., Inc., I respectfully request the NCCN Non-Small Cell Lung Cancer Panel review the enclosed information for inclusion of KEYTRUDA (pembrolizumab) in the NCCN Clinical practice guidelines in Oncology.

FDA Clearance:

The FDA approved KEYTRUDA for treatment of metastatic NSCLC whose tumors express PD-L1 as determined by an FDA-approved test and who have disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving KEYTRUDA.

Rationale:

In support of the requested change, FDA approval was based on results from a sub-group of patients enrolled in a multicenter, open-label multi-cohort, activity-estimating study which demonstrated significant tumor response rates and durability of response in patients with metastatic non-small cell lung cancer.

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.
3. Goldberg et al. A Phase II Trial of Pembrolizumab for Untreated Brain Metastases from Non-Small Cell Lung Cancer. 16th World Conference on Lung Cancer. Denver, Colorado. September 9, 2015.


KEYTRUDA_pi.pdf


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Goldberg

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

Sincerely,

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