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NCCN Guidelines Panel: melanoma

On behalf of Merck & Co., Inc., I respectfully request the NCCN Panel review the enclosed information for KEYTRUDA (pembrolizumab) on the NCCN Treatment Guidelines of Melanoma.

Specific changes requested:

In section ME-E we respectfully request that KEYTRUDA be upgraded from category 2a to category 1 for systemic therapy for patients with advanced melanoma.

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.

This indication is approved under accelerated approval based on tumor response rate and durability of response. An improvement in survival or disease-related symptoms has not yet been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Rationale:

In an article published in The New England Journal of Medicine, April 19, 2015, Robert et al reported results from a randomized, controlled, phase 3 study which assessed progression-free survival and overall survival of pembrolizumab (10 mg/kg every 2 weeks or every 3 weeks) versus four doses of ipilimumab at 3 mg/kg every 3 weeks. The estimated 6-month progression-free survival rates were 47.3% for pembrolizumab every 2 weeks, 46.4% for pembrolizumab every 3 weeks, and 26.5% for ipilimumab; estimated 12-month survival rates were 74.1%, 68.4%, and 58.2%, respectively.

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

1. KEYTRUDA (pembrolizumab) prescribing information. Merck & Co., Inc.

2. Robert et. Al., Pembrolizumab versus Ipilimumab in Advanced Melanoma. *The New England Journal of Medicine*. April 19, 2015.


NEJM robert.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,

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