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Date of Request: June 16, 2020
NCCN Guidelines Panel: Melanoma Panel

NCCN Melanoma Panel: On behalf of Merck & Co., Inc., I respectfully request the NCCN Melanoma Panel to review the enclosed information for KEYTRUDA® (pembrolizumab), in reference to unresectable or metastatic melanoma.

Specific Changes: We respectfully request the inclusion of pembrolizumab in combination with low-dose ipilimumab as a second-line or subsequent treatment option for patients with confirmed progression of unresectable or metastatic melanoma after treatment with an anti-PD1 antibody in the appropriate sections of the NCCN Cutaneous Melanoma Guidelines v3.2020, including page ME-I (1 of 7).

FDA Clearance: KEYTRUDA (pembrolizumab) is indicated for the treatment of patients with unresectable or metastatic melanoma.

Please refer to the KEYTRUDA prescribing information for other FDA-approved indications.¹

Rationale: Treatment options for metastatic melanoma following anti-PD1 antibody failure are limited. Olson et al. presented data from a phase II trial of patients with unresectable or metastatic melanoma (n=70) with confirmed progression after treatment with an anti-PD1 antibody. Patients received pembrolizumab 200 mg IV every 3 weeks (Q3W) in combination with ipilimumab 1 mg/kg Q3W for 4 doses. The primary endpoint was immune-mediated response per irRECIST. The response rate was 27% (19/70), with a median duration of response of 18.5 months (95% CI, 10.6-undetermined). The median overall survival was 24.7 months (95% CI, 15.2-undetermined). Grade 3 and Grade 4 adverse events occurred in 26% (18/70) and 1% (1/70) of patients, respectively. The results of this study of pembrolizumab in combination with low-dose ipilimumab demonstrated antitumor activity in patients with confirmed progression of unresectable or metastatic melanoma after treatment with an anti-PD1 antibody.²

The following resources are submitted to assist the committee with their review:

1. KEYTRUDA (pembrolizumab) Prescribing Information. Merck & Co., Inc.
2. Olson DJ, Luke JJ, Poklepovic AS, et al. Significant antitumor activity for low-dose ipilimumab (IPI) with pembrolizumab (PEMBRO) immediately following progression on PD1 Ab in melanoma (MEL) in a phase II trial. Presented at: American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program; *J Clin Oncol* 2020;38(suppl);abstr 10004.

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 'Suzana Giffin', with a horizontal line extending to the right.

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