

Name: Suzana Giffin, AVP
Company/Organization: Merck & Co., Inc.
Address: 2000 Galloping Hill Rd. Kenilworth, NJ 07033
Phone: 908-740-6708
Email: suzana.giffin@merck.com
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NCCN Guidelines Panel: Non-Melanoma Skin Cancers Panel

NCCN Non-Melanoma Skin Cancers Panel: On behalf of Merck & Co., Inc., I respectfully request the NCCN Non-Melanoma Skin Cancers Panel to review the enclosed information for KEYTRUDA (pembrolizumab), in reference to NCCN Basal Cell Skin Cancer Guidelines.

Specific Changes: We respectfully request that the recommendation for pembrolizumab in the treatment of advanced MSI-H basal cell skin cancer be added as a category 2A (page BCC-4) and that the Discussion section (page MS-11) in the NCCN Basal Cell Skin Cancer Guidelines be updated, based on the efficacy data from the publication by Marabelle et al.

FDA Clearance: KEYTRUDA (pembrolizumab) is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

Rationale: Based on the clinically meaningful results, durable responses and unmet medical needs, the totality of data in the study supports our request for a Category 2A recommendation for pembrolizumab.

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

1. KEYTRUDA (pembrolizumab) prescribing information. Merck & Co., Inc.
2. Marabelle et al. Efficacy of pembrolizumab in patients with noncolorectal high microsatellite instability/mismatch repair-deficient cancer: results from the phase 2 KEYNOTE-158 study. *Journal of Clinical Oncology* 2019.

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

Sincerely,



Suzana Giffin, AVP
Merck & Co., Inc.

2000 Galloping Hill Rd
Kenilworth, NJ 07033
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suzana.giffin@merck.com