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Date of Request: 03/20/2020
NCCN Guidelines Panel: Prostate Cancer

NCCN Prostate Cancer Panel: On behalf of Merck & Co., Inc., I respectfully request the NCCN Prostate Cancer Panel to review the enclosed information for KEYTRUDA (pembrolizumab), in reference to NCCN Prostate Cancer Guidelines.

Specific Changes: We respectfully request that the recommendation for pembrolizumab in the second-line and subsequent treatment of advanced MSI-H prostate cancer be changed from category 2B to category 2A (page PROS-16) and that the Discussion section (page MS-45) in the NCCN Prostate 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. J Clin Oncol 38:1-10.

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

Sincerely,

Suzana Giffin, AVP
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