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

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

Specific Changes: We respectfully request that the updated publication by Marabelle et al. be added as a reference to support pembrolizumab as a treatment option for patients with MSI-H vulvar cancer (page VULVA-E) and that this reference be considered in the Discussion section (page MS-15) of the NCCN Vulvar Cancer Guidelines.

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 an updated reference 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,



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