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
Date of Request: 03/19/2020
NCCN Guidelines Panel: Cervical/Uterine Cancers

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

Specific Changes: We respectfully request that the recommendation for pembrolizumab in the treatment of unresectable or metastatic, MSI-H/dMMR endometrial tumors be changed from category 2A to category 1 (page ENDO-D 1 of 2) and that the Discussion section for systemic therapy for recurrent or metastatic endometrial cancer (page MS-20) be updated, based on the efficacy data from the updated 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 1 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
Merck & Co., Inc.
2000 Galloping Hill Rd
Kenilworth, NJ 07033
908-740-6708
suzana.giffin@merck.com