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Date of Request: 03/12/2020
NCCN Guidelines Panel: Esophageal/Gastric Cancers

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

Specific Changes: We respectfully request that KEYTRUDA (pembrolizumab) and KEYTRUDA (pembrolizumab) plus chemotherapy is recommended as first line treatment option for MSI-H/dMMR Gastric/GEJ Cancer based on post hoc analysis from KN 062 study and presented by Shitara et al. and Chao et al.; we also request that references supporting pembrolizumab as treatment for MSI-H gastric cancer in second line treatment or beyond be updated to Marabelle et al. and the presentation by Shitara et al. and that the efficacy data be incorporated in the NCCN Guidelines under Category 1 for second line treatment.

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, characterized by durable responses in a setting of unmet medical needs, the totality of data in the study as reported in the references cited supports our request for the 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.
3. Shitara et al. Pembrolizumab with or without chemotherapy versus chemotherapy in patients with advanced G/GEJ Cancer including outcomes according to microsatellite instability-high status in KEYNOTE-062. Presented at 2019 ESMO Annual Meeting: Sept 27-Oct 1; Barcelona, Spain.
4. Chao et al. Pembrolizumab in microsatellite instability-high advanced Gastric/Gastroesophageal Junction cancer by line of therapy. Presented at 2020 ASCO GI Meeting: Jan 23-25; San Francisco, USA.

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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