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Date of Request: June 18<sup>th</sup>, 2020  
NCCN Guidelines Panel: Head and Neck Cancers

NCCN Head and Neck Cancers Panel: On behalf of Merck & Co., Inc., I respectfully request the NCCN Head and Neck Cancers Panel to review the enclosed information for KEYTRUDA® (pembrolizumab), in reference to Head and Neck Cancers.

Specific Changes: We respectfully request an increase in the number of Evidence Blocks for efficacy of the regimen for pembrolizumab combination therapy (pembrolizumab/platinum/5-FU) on page SYST-A EB-3 from NCCN Head and Neck Cancers Guidelines Version 1.2020, NCCN Evidence Blocks.

FDA Clearance:

*Head and Neck Squamous Cell Cancer*

- KEYTRUDA, in combination with platinum and fluorouracil (FU), is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC).
- KEYTRUDA, as a single agent, is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 [Combined Positive Score (CPS)  $\geq 1$ ] as determined by an FDA-approved test.
- KEYTRUDA, as a single agent, is indicated for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.

Please refer to the KEYTRUDA prescribing information for other FDA-approved indications.<sup>1</sup>

Rationale: Data suggests an overall survival advantage for patients treated with pembrolizumab/platinum/5-FU when compared to cetuximab/platinum/5-FU for first-line treatment of recurrent/metastatic head and neck squamous cell carcinoma (page SYST-A 2 of 6 from NCCN Head and Neck Cancers Guidelines Version 1.2020, NCCN Evidence Blocks). In the KEYNOTE-048 phase III trial, the median overall survival for pembrolizumab/platinum/5-FU versus EXTREME was 13.0 months versus 10.7 months (HR = 0.77; 95% CI 0.63-0.93; P-value = 0.0034).<sup>2</sup> Currently, however, the cetuximab/platinum/5-FU regimen has 4 blocks for efficacy while pembrolizumab/platinum/5-FU has only 3 blocks for efficacy.

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

1. KEYTRUDA (pembrolizumab) prescribing information. Merck & Co., Inc.
2. Burtneß B, Harrington KJ, Greil R, et al. Pembrolizumab alone or with chemotherapy versus cetuximab with chemotherapy for recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-048): a randomised, open-label, phase 3 study. *Lancet*. 2019 Nov 23;394(10212):1915-1928.

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 'S. Giffin', with a horizontal line extending to the right.

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