

September 23, 2020

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Vice President & Head, US Medical Oncology  
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**NCCN Guidelines® Panel: Gastric Cancer**

Dear Panel Members,

On behalf of Bristol Myers Squibb Company, I respectfully submit the enclosed Opdivo® (nivolumab) clinical data that was presented at the 2020 European Society for Medical Oncology (ESMO) Annual Meeting to the NCCN Gastric Cancer Panel for your consideration.<sup>1</sup>

CheckMate 649 is a global, randomized, open-label, phase 3 study, which evaluated nivolumab plus chemotherapy in the first-line setting for patients with advanced gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma (GC/GEJC/EAC). Patients with previously untreated, unresectable, advanced or metastatic GC/GEJC/EAC were randomized (1:1:1) to receive nivolumab plus ipilimumab, nivolumab plus chemotherapy (1 of 2 regimens: oxaliplatin plus leucovorin plus fluorouracil [FOLFOX] or oxaliplatin plus capecitabine [CapeOX]), or chemotherapy alone. The dual primary endpoints were overall survival (OS) and progression-free survival (PFS) in patients whose tumors expressed PD-L1 CPS  $\geq 5$ . Secondary endpoints included OS and PFS in all randomized patients. The first results of the CheckMate 649 study, comparing nivolumab plus chemotherapy versus chemotherapy alone (N = 1581, including 955 patients with PD-L1 CPS  $\geq 5$ ), were presented at the 2020 ESMO Annual Meeting.<sup>1</sup>

**Specific Changes:** I request that the Panel consider the inclusion of nivolumab in combination with FOLFOX or CapeOX as a Category 1 treatment option for patients with previously untreated, unresectable, advanced or metastatic gastric cancer (GAST-F, page 3 of 14).

**FDA Clearance in Gastric Cancer:** The use of nivolumab plus chemotherapy as first-line treatment for unresectable, advanced or metastatic GC/GEJC/EAC is considered investigational.<sup>2</sup>

**Rationale:** This information is being submitted in response to a standing request from NCCN for new data.

As part of this submission, the following resources are included for your review. We would like to acknowledge the contributions of NCCN panel members who are also co-authors of the presentation.

1. Moehler M, Shitara K, Garrido M, et al. Nivolumab plus chemotherapy versus chemotherapy as first-line treatment for advanced gastric cancer/gastroesophageal junction cancer/esophageal adenocarcinoma: first results of the CheckMate 649 study. Oral Presentation presented at the European Society for Medical Oncology (ESMO) 2020 Annual Meeting; September 19- 21, 2020; Virtual Meeting.
2. Product information, OPDIVO® (nivolumab) injection, for intravenous infusion. Bristol Myers Squibb Company, Princeton, NJ. September 2020.

Thank you for your consideration of this request.

Sincerely,

A handwritten signature in black ink that reads "Samantha Gothelf". The script is fluid and cursive, with the first name and last name clearly legible.

Samantha Gothelf, PharmD  
Vice President & Head, US Medical Oncology