

December 4, 2019
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Bristol-Myers Squibb Company
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NCCN Guidelines® Panel: Uterine Cancers Panel

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit to the panel the enclosed Opdivo® (nivolumab) clinical data that was recently published in the *Journal of Clinical Oncology (J Clin Oncol)*. This information is being submitted for the Panel's consideration.

The National Cancer Institute-Molecular Analysis for Therapy Choice (NCI-MATCH) is a multicenter trial that evaluated patients with relapsed/refractory malignancies who were assigned to treatments in parallel phase 2 studies based on tumor molecular alterations. Arm Z1D is a phase 2, open-label, single arm study of the NCI-MATCH trial that evaluated the use of nivolumab in patients with deficient mismatch repair (dMMR), non-colorectal cancers including endometrioid endometrial adenocarcinoma, uterine carcinosarcoma/malignant mixed Mullerian tumor, and leiomyosarcoma of uterus.¹

The use of nivolumab for patients with uterine neoplasms are considered investigational.²

FDA Clearance of Opdivo® (nivolumab) [indication in high microsatellite instability (MSI-H) or dMMR metastatic colorectal cancer]:

- Adult and pediatric (12 years and older) patients with MSI-H or dMMR metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, as a single agent or in combination with ipilimumab.²

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

As part of the submission, the following resources are included for your review:

1. Azad NS, Gray RJ, Overman MJ, et al. Nivolumab is effective in mismatch repair-deficient noncolorectal cancers: results from arm Z1D-a subprotocol of the NCI-MATCH (EAY131). *J Clin Oncol*. 2019. doi:10.1200/JCO.19.00818. [Epub ahead of print].
2. Product information, OPDIVO® (nivolumab) injection, for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. September 2019.

Thank you for your consideration of this request.

Sincerely,



Awny Farajallah, MD, FACP
Vice President, Head US Medical
Bristol-Myers Squibb Company