

October 17, 2019
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NCCN Guidelines® Panel: Cervical Cancer 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)* and presented at the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting. This information is being submitted for the Panel's consideration.

The CheckMate 358 study, which was published in *J Clin Oncol* 2019, is a phase 1/2, multicenter, open-label, multicohort study that evaluated the safety and efficacy of nivolumab-based therapies in patients with virus-associated solid tumors in the neo-adjuvant or recurrent/metastatic setting. Nivolumab monotherapy was evaluated for use in patients with recurrent/metastatic cervical and vaginal/vulvar cancer.¹

ONO 039, which was presented at ASCO 2018, is a phase 2, open-label study that evaluated the efficacy and safety of nivolumab monotherapy in Japanese patients for the treatment of advanced or recurrent uterine cervical cancer, uterine corpus cancer, or soft tissue sarcoma.²

FDA Clearance: The use of nivolumab for patients with recurrent/metastatic cervical cancer is considered investigational.³

Rationale: These data are 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. Naumann RW, Hollebecque A, Meyer T, et al. Safety and efficacy of nivolumab monotherapy in recurrent or metastatic cervical, vaginal, or vulvar carcinoma: results from the phase I/II CheckMate 358 trial. *J Clin Oncol*. 2019. doi: 10.1200/JCO.19.00739. [Epub ahead of print].
2. Hasegawa K, Tamura K, Katsumata N, et al. Efficacy and safety of nivolumab in patients with advanced or recurrent uterine cervical or corpus cancers. Poster presented at American Society of Clinical Oncology (ASCO) Annual Meeting; June 1-5, 2018; Chicago, IL, USA.
3. 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