June 4, 2020
Samantha Gothelf, PharmD
Vice President, Head US Medical Oncology
Bristol Myers Squibb
3401 Princeton Pike
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NCCN Guidelines® Panel: Ovarian Cancer Panel

Dear Panel Members,

On behalf of Bristol Myers Squibb, I respectfully submit to the panel the enclosed OPDIVO® (nivolumab) plus YERVOY® (ipilimumab) clinical data that was recently published in *Journal of Clinical Oncology (J Clin Oncol)* on April 10, 2020.

The NRG GY003 study is a phase 2, randomized, open-label trial that evaluated nivolumab monotherapy versus nivolumab plus ipilimumab for the treatment of patients with recurrent or persistent ovarian cancer.[1]

Specific Changes: I request that the Panel consider recommending nivolumab with or without ipilimumab as a treatment option for patients with:

- recurrent platinum-sensitive ovarian cancer under useful in certain circumstances (OV-C page 7 of 10)
- recurrent platinum-resistant ovarian cancer under useful in certain circumstances (OV-C page 8 of 10)

FDA Clearance in Ovarian Cancer: The uses of nivolumab monotherapy and nivolumab plus ipilimumab for the treatment of patients with ovarian cancer are considered investigational.[2,3]

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. Zamarin D, Burger RA, Sill MW, et al. Randomized Phase II Trial of Nivolumab Versus Nivolumab and Ipilimumab for Recurrent or Persistent Ovarian Cancer: An NRG Oncology Study. *J Clin Onco*l. 2020. doi: 10.1200/JCO.19.02059. [Epub ahead of print].
2. Product information, OPDIVO® (nivolumab) injection, for intravenous infusion. Bristol Myers Squibb Company, Princeton, NJ. May 2020.
3. Product information, YERVOY® (ipilimumab) injection, for intravenous infusion. Bristol Myers Squibb Company, Princeton, NJ. May 2020.

Thank you for your consideration of this request.

Sincerely,

Samantha Gothelf, PharmD
Vice President, Head US Medical Oncology
Bristol Myers Squibb