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July 11, 2018
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**NCCN Guidelines® Panel: Colon/Rectal/Anal Cancers**

Dear Panel Members:

On behalf of Bristol-Myers Squibb Company, I respectfully submit to the panel the enclosed prescribing information for OPDIVO® (nivolumab) with an updated indication. With this update, nivolumab is now approved for the treatment of adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, in combination with ipilimumab.[1,2] This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.[1]

**FDA Clearance:** The FDA approved OPDIVO® in combination with ipilimumab on July 10, 2018 for the treatment of 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.[1,2]

Additionally, OPDIVO® is indicated as monotherapy for the treatment of 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.

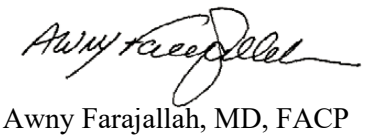
**Rationale:** This data is being submitted in response to a standing request from NCCN for new clinical data. Data from the Phase 2 study, CheckMate 142, on the use nivolumab and ipilimumab combination for the treatment of patients with MSI-H or dMMR metastatic colorectal cancer after prior therapy was submitted to NCCN on January 22, 2018.

The following resources are included for your review:

1. Product information, OPDIVO® (nivolumab) injection, for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. July 2018.
2. Product information, YERVOY® (ipilimumab) injection, for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. July 2018.

Thank you for your consideration of this request.

Sincerely,



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