Submitted by:
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**NCCN Guidelines® Panel: Melanoma**

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit to the panel the prescribing information for OPDIVO® (nivolumab) with an updated indication. With this update, nivolumab is now approved for the adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.[1]

**Specific Changes:** I respectfully request you to consider changing the recommendation of Category 1 (preferred adjuvant immunotherapy regimen) designation of "Nivolumab for resected Stage IIIB/C" to "Nivolumab" (Page ME-4).

**FDA Clearance OPDIVO (nivolumab) (indications in melanoma):** The FDA approved OPDIVO® (nivolumab) on December 20, 2017 for the adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.[1]

Additionally, nivolumab is indicated in melanoma:[1]

- patients with BRAF V600 wild-type unresectable or metastatic melanoma, as a single agent.
- patients with BRAF V600 mutation-positive unresectable or metastatic melanoma, as a single agent. This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.
- patients with unresectable or metastatic melanoma, in combination with ipilimumab. This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

**Rationale**: The clinical evidence from the registrational, randomized, Phase 3 study of nivolumab versus ipilimumab 10 mg/kg in patients with completely resected Stage IIIB, IIIC, or IV melanoma (based on AJCC 7th edition criteria) was submitted for your consideration on September 11, 2017. The FDA has now approved the adjuvant melanoma indication above that encompasses completely resected Stage III and IV patients.[1]

The following resource is included for your review:

1. Product Information, OPDIVO® (nivolumab) injection for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. December 2017.

Thank you for your consideration of this request..

Sincerely,

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