

Submitted by:

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NCCN Guidelines® Panel: Non-Small Cell Lung Cancer (NSCLC)

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully request the Panel to consider recommending nivolumab in the NCCN Guidelines as a Category 1 agent for the treatment of metastatic NSCLC, regardless of histology, with progression on or after platinum-based chemotherapy.

Specific Changes: We request to modify the listing of nivolumab for the treatment of metastatic non-squamous NSCLC with progression on or after platinum-based chemotherapy (page NSCL-19) to Category 1 level evidence. Also, we request the Panel to consider moving nivolumab up on the list ahead of docetaxel as a treatment option for non-squamous histology, similar to squamous histology (page NSCL-20).

FDA Clearance: The FDA approved OPDIVO® (nivolumab) on October 9, 2015 for the treatment of metastatic NSCLC in patients with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving OPDIVO.¹ On March 4, 2015 Opdivo was approved for the treatment of patients with metastatic squamous cell NSCLC after platinum-based chemotherapy. The other currently approved indications for nivolumab (accelerated approval) are in unresectable or metastatic melanoma.¹

Rationale: The FDA has now approved nivolumab for the treatment of patients with metastatic NSCLC, regardless of histology.

The clinical evidence from the registrational randomized Phase 3 study of nivolumab vs docetaxel in patients with stage IIIB or IV non-squamous cell NSCLC, who have progressed during or after one platinum doublet-based chemotherapy regimen, was presented at ASCO 2015 and was submitted for your consideration on June 5, 2015. The data are now published in NEJM.²

The following resources are included for your review in support of this proposed inclusion/change:

1. Product information, OPDIVO® (nivolumab) injection for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. October 2015.
2. Borghaei H, Paz-Ares L, Horn L, et al. Nivolumab versus Docetaxel in Advanced Nonsquamous Non-Small-Cell Lung Cancer. New England Journal of Medicine; published online ahead of print, 27 Sept 2015, NEJM.org. DOI: 10.1056/NEJMoa1507643.

We acknowledge the contributions of NCCN panel members who are also co-authors or co-contributors of this publication. Thank you for your consideration of this request.

Sincerely,

A handwritten signature in black ink, appearing to read "Awny Farajallah". The signature is fluid and cursive, with a large, stylized initial "A" and "F".

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