



May 26, 2020

Samantha Gothelf, PharmD
Vice President, Head US Medical Oncology
Bristol Myers Squibb Company
3401 Princeton Pike
Lawrence Township, NJ 08648

NCCN Guidelines® Panel: Non-Small Cell Lung Cancer Panel

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit the enclosed OPDIVO® (nivolumab) and YERVOY® (ipilimumab) prescribing information updated with a new indication. With this update, nivolumab in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy, is now approved for the first-line treatment of adult patients with metastatic or recurrent non-small cell lung cancer (NSCLC) with no EGFR or ALK genomic tumor aberrations.^{1,2}

Specific Changes: I request that nivolumab in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy, be added to the NCCN Guidelines as a preferred Category 1 recommendation as a treatment option for the first-line treatment of patients with metastatic or recurrent NSCLC with no EGFR or ALK genomic tumor aberrations, regardless of histology or PD-L1 expression (NSCL-30, NSCL-31, and NSCL-J [2 and 3 of 4]).

FDA Clearance in Non-small Cell Cancer:

The FDA approved OPDIVO® in combination with YERVOY® and 2 cycles of platinum-doublet chemotherapy, on May 26, 2020, for the first-line treatment of adult patients with metastatic or recurrent NSCLC with no EGFR or ALK genomic tumor aberrations.^{1,2}

OPDIVO® in combination with YERVOY® is also indicated for the first-line treatment of adult patients with metastatic NSCLC whose tumors express PD-L1 ($\geq 1\%$) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.^{1,2}

Additionally, OPDIVO® is indicated as monotherapy for the treatment of patients with metastatic NSCLC 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

Rationale: This data is being submitted in response to a standing request from NCCN for new clinical data. The new FDA approved indication is based on results from CheckMate 9LA. CheckMate 9LA is a Phase 3, randomized, open-label study which evaluated nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy as a first-line treatment in patients with advanced non-small cell lung cancer across non-squamous and squamous tumor histologies, regardless of PD-L1 expression.^{1,2} Results from CheckMate 9LA are planned to be presented at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting and will be submitted to this panel once available.

As part of this submission, the following resources are included for your review:

1. Product Information, OPDIVO® (nivolumab) injection for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. May 2020.
2. 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 Company