Bristol Myers Squibb™

May 15, 2020

Samantha Gothelf, PharmD
Vice President, US Oncology Medical
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 is now approved for the first-line treatment of adult patients with metastatic NSCLC whose tumors express PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.[1,2]

Specific Changes: I request that nivolumab in combination with ipilimumab be a preferred Category 1 recommendation in the NCCN Guidelines as a treatment option for the first-line treatment of adult patients with metastatic NSCLC with no EGFR or ALK genomic tumor aberrations, regardless of histology, in patients with PD-L1 expression ≥1% (NSCL-30 and NSCL-31).

FDA Clearance in Non-small Cell Cancer:

The FDA approved OPDIVO® in combination with YERVOY® on May 15, 2020 for the first-line treatment of adult patients with metastatic NSCLC whose tumors express PD-L1 (≥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 Part 1a of the CheckMate 227 study. CheckMate 227 is a Phase 3, randomized, multi-part, open-label study which evaluated nivolumab-based regimens versus platinum-doublet chemotherapy as a first-line treatment in patients with advanced non-small cell lung cancer across non-squamous and squamous tumor histologies. The Part 1 analysis from this study was previously submitted to the NCCN on September 28, 2020.[1,2]

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

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