March 6, 2018

NCCN Guidelines® Panel: Hepatobiliary Cancers

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit the enclosed OPDIVO® (nivolumab) prescribing information and clinical data which supports the most recent label change, that occurred on March 5, 2018 to reflect the new dosing for nivolumab to 240 mg administered intravenously every 2 weeks or 480mg administered intravenously every 4 weeks over 30 minutes.¹ This information is being sent to the NCCN® Hepatobiliary Cancers Panel for your consideration.

Specific Changes: Request for the inclusion as a footnote to HCC-5 and HCC 6, the following: nivolumab FDA approved dose is 240mg IV every 2 weeks or 480mg IV every 4 weeks administered over 30 minutes until disease progression or unacceptable toxicity.¹

FDA Clearance of OPDIVO® (nivolumab) (indication in Hepatocellular Carcinoma):
- OPDIVO® is indicated for the treatment of patients with hepatocellular carcinoma who have been previously treated with sorafenib

Rationale: The Opdivo Prescribing Information was updated to reflect the new dosing of Opdivo to 240mg administered intravenously every 2 weeks or 480mg administered intravenously every 4 weeks over 30 minutes for all indications, except for metastatic colorectal cancer which is to be dosed at 240mg administered intravenously every 2 weeks over 30 minutes.¹ The dosing recommendation stated in the product label is different than the dose that was administered in the registrational clinical studies that supported the current approved indications.

As part of this submission, the published literature that support the pharmacokinetic analyses for the dosing of 240mg every 2 weeks, 480mg every 4 weeks, and a 30 minute infusion time are enclosed for your review.²-⁴

Thank you for your consideration.
Sincerely,

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