NCCN Guidelines® Panel: Kidney Cancer

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 second-line treatment of advanced renal cell carcinoma (RCC).

Specific Changes: We request that nivolumab be recommended with a Category 1 designation for the treatment of patients with relapsed or Stage IV, surgically unresectable clear cell RCC that has been previously treated with anti-angiogenic therapy (page KID-3).

FDA Clearance: The FDA approved OPDIVO® (nivolumab) on November 23, 2015 for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy. Other currently approved indications for nivolumab are:

- Unresectable or metastatic melanoma (accelerated approval)
  - as a single agent in patients with disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor.
  - in combination with ipilimumab in patients with BRAF V600 wild-type melanoma.
- Metastatic non-small cell lung cancer in patients with progression on or after platinum-based chemotherapy.

Rationale: The clinical evidence from the registrational, randomized, Phase 3 study of nivolumab versus everolimus in patients with advanced RCC who were previously treated with anti-angiogenic therapy, was submitted for your consideration on September 28, 2015. The submission also included the 3-year survival data from Phase 1 and 2 studies in patients with advanced RCC. The FDA has now approved the RCC indication mentioned above.

The following resources are included for your review in support of this proposed inclusion. We would like to acknowledge the contributions of NCCN panel members who are also co-authors or co-contributors of some of these publications/presentations.

3. Plimack ER, Hammers HJ, Rini BI et al. Updated Survival Results From a Randomized, Dose-Ranging Phase II study of Nivolumab in Metastatic Renal Cell Carcinoma. Poster presented at: 51st Annual American Society of Clinical Oncology (ASCO) Meeting; May 29-June 2, 2015; Chicago, IL, USA.

Thank you for your consideration of this request.

Sincerely,

[Signature]

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