Submitted by:
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NCCN Clinical Practice Guidelines® Panel: Melanoma

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company (BMS), I respectfully request that the NCCN Melanoma Panel review the enclosed communication from the Food and Drug Administration (FDA)[1] releasing the Risk Evaluation and Mitigation Strategy (REMS) from Yervoy® (ipilimumab) and remove all reference to the Yervoy REMS within the guidelines.

Specific Changes: I respectfully request revision of the NCCN REMS resource tool web page to indicate the release of the Yervoy REMS on 3/16/2015 and respectfully request the removal of Yervoy REMS-related recommendations and references noted in the NCCN Melanoma Guidelines v3.2015, page ME-F (1 of 3), Principles of Immunotherapy and Targeted Therapy, Ipilimumab, Management of Toxicities, sub-bullets 1 and 2 which read as follows:

- "Ipilimumab has the potential for significant immune-mediate complications. Participation in the Risk Evaluation and Mitigation Strategy (REMS) program and/or experience in use of the drug as well as resources to follow the patient closely are essential. Ipilimumab should be used with extreme caution, if at all, in patients with serious underlying autoimmune disorders"
- "For more information on toxicities associated with ipilimumab and the management of these toxicities, see the REMS document (www.fda.gov/downloads/drugs....) and the full prescribing information for ipilimumab (www.fda.gov)."

FDA Clearance: The FDA originally approved the Yervoy REMS on March 25, 2011 consisting of a communication plan and a timetable for submission of assessment of the REMS. On March 16, 2015 the FDA determined due to the completion of key activities under the communication plan and demonstration that the communication plan has met its goal and it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks. Because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Yervoy.

Rationale for Proposed Change: Since the REMS for Yervoy is no longer in effect, information provided on the NCCN REMS resource tool and delineated within the guidelines is no longer accurate.

The following resource is included for your review in support of this proposed inclusion/change:

[1] Department of Health and Human Services, Food and Drug Administration, Yervoy (ipilimumab) Risk Evaluation and Mitigation Strategy release notification letter, March 16, 2015.

Thank you for your consideration of this request.

Sincerely,

Joseph Leveque, MD
Vice President, US Medical Oncology
Bristol-Myers Squibb Company