

NCCN Melanoma V.1.2015 – Interim Teleconference – October 3, 2014

Guideline Page and Request	Panel Discussion	References	Vote		
			YES	NO	ABSTAIN
<p>ME-E (1 of 4) Internal request: Based on the recent FDA approval for pembrolizumab for the treatment of patients with advanced or unresectable melanoma who are no longer responding to other drugs, review the data for its inclusion in the NCCN Guidelines for Melanoma.</p> <p>External request: (Submission) Add pembrolizumab to the NCCN Guidelines for Melanoma as systemic therapy for patients with unresectable or metastatic melanoma.</p> <p>External request: (Submission) Add pembrolizumab to the NCCN Guidelines for Melanoma as systemic therapy for patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 positive, a BRAF inhibitor.</p>	<p>Based upon the FDA approval, review of the data in the noted references, and discussion, the panel consensus was to add pembrolizumab to the NCCN Guidelines for Melanoma as an option for the treatment of advanced or metastatic melanoma with the following footnote: “Pembrolizumab is indicated for disease progression after treatment with ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. Pembrolizumab may cause immune-mediated adverse reactions. Depending on the severity of the reaction, pembrolizumab should be discontinued and corticosteroids administered for immune-mediated: pneumonitis, colitis, hepatitis, hypophysitis, nephritis, and hyperthyroidism. For patients with pre-existent hypophysitis due to ipilimumab, pembrolizumab may be administered if patients are on appropriate physiologic replacement endocrine therapy.”</p> <p>A second vote resulted in the panel deciding to add pembrolizumab to the list of “Other Active Regimens”. Vote results are as follows: Other Active Regimens: 16 Preferred Regimens: 3 Abstain: 1</p>	<ol style="list-style-type: none"> 1. Robert C, Ribas A, Wolchok JD, et al. Anti-programmed-death-receptor-1 treatment with pembrolizumab in ipilimumab-refractory advanced melanoma: a randomised dose-comparison cohort of a phase 1 trial. <i>Lancet</i> 2014;384:1109-1117. 2. Hamid O, Robert C, Daud A, et al. Safety and Tumor Responses with Lambrolizumab (Anti-PD-1) in Melanoma. <i>N Eng J Med</i> 2013;369:134-144. 3. See Submissions for other references. 	19	0	1

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Guideline Page and Request	Panel Discussion	References	Vote		
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<p>ME-E (1 of 4) Internal request: Panel member request to review recent data presented at the European Society for Medical Oncology (ESMO) conference and consider recommending the combination of “dabrafenib + trametinib” over single-agent dabrafenib.</p>	<p>Based on a review of the data and discussion, the panel noted that combination therapy is preferred over single-agent therapy (with the exception of ipilimumab). The panel consensus was to move single-agent “Dabrafenib (category 1)” from “Preferred Regimens” to “Other Active Regimens” for advanced or metastatic melanoma.</p>		18	1	1
<p>ME-E (1 of 4) Internal request: Move single-agent vemurafenib from “Preferred Regimens” to “Other Active Regimens” for advanced or metastatic melanoma.</p>	<p>Based on a review of the data and discussion, the panel agreed that combination therapy is preferred over single-agent therapy (with the exception of ipilimumab). The panel consensus was to move single-agent “Vemurafenib (category 1)” from “Preferred Regimens” to “Other Active Regimens” for advanced or metastatic melanoma.</p>		18	1	1