

NCCN Guidelines for Melanoma V.1.2017–Panel Teleconference on 07/22/16

Guideline Page and Request	Panel Discussion/References	Vote			
		YES	NO	ABSTAIN	ABSENT
<p><u>ME-1</u> External Submission: Oregon Health and Science University request to add a data-based recommendation for attainment of personal and family history of melanoma along with recommendations for counseling and testing of appropriate individuals.</p> <p><u>ME-1</u> External Submission: Myriad Genetic Laboratories, Inc. request to add a recommendation for genetic risk assessment/testing for individuals meeting specified personal and family history criteria to the Initial Clinical Assessment algorithm for newly diagnosed patients and as part of the discussion of risk factors.</p>	<p>The following changes were made to address these submissions:</p> <ul style="list-style-type: none"> • A new section for "Risk Factors for Melanoma Development" was added that lists risks for developing single or multiple primary melanomas, including subsequent primaries after index diagnosis, along with supporting citations.(ME-A) This section includes "Genetic Predisposition" as a risk factor for melanoma development, with the bullets "Presence of melanoma polymorphisms (including CDKN2A, CDK4, MC1R, and other as yet undefined germline mutations)" and "Family history of melanoma, especially if multiple". • As part of "Common Follow-up Recommendations for All Patients", in footnote "ff" on ME-8 and ME-9, a new bullet was added: "Consider referral to a genetics counselor for p16/CDKN2A mutation testing in the presence of 3 or more invasive melanomas, or a mix of invasive melanoma and pancreatic cancer diagnoses in an individual or family." 	21	0	0	6
<p><u>ME-1</u> External Submission: Castle Bioscience, Inc request to consider inclusion of gene expression profiling in the Melanoma Guidelines as a prognostic test by modifying footnotes "c" and "cc".</p>	<p>Based on a review of the data and discussion, the panel agreed not to include gene expression profiling as part of routine prognostic testing recommended in the NCCN Guidelines for Melanoma. The panel consensus was that the data was currently too premature and it will wait for publication of further studies before reconsidering including gene expression profiling in the Guidelines.</p>	0	19	0	8
<p><u>ME-G 1 of 6</u> External Submission: Merck & Co, Inc. request that first-line pembrolizumab be updated from category 2A to category 1 for the treatment of metastatic or unresectable melanoma.</p>	<p>Based on a review of data and discussion of KEYNOTE-006, the panel consensus supported changing pembrolizumab from category 2A to category 1 for first-line treatment of metastatic or unresectable melanoma:</p> <ul style="list-style-type: none"> • Robert C, Schachter J, Long GV, et al. Pembrolizumab versus ipilimumab in advanced melanoma. N Engl J Med 2015;372:2521-2532. Available at: http://www.ncbi.nlm.nih.gov/pubmed/25891173. 	19	0	0	8

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<p><u>ME-G 1 of 6</u> Panel member request: Re-discuss the data for single agent vemurafenib and dabrafenib for first- and second-line or subsequent treatment of metastatic or unresectable melanoma.</p>	<p>Based on review of the data and discussion of their preference for combination BRAF/MEK inhibitor therapy over BRAF inhibitor monotherapy except in cases for patients with comorbidities or cannot tolerate immunotherapy, panel consensus supported moving single-agent vemurafenib and dabrafenib as first- and second-line or subsequent treatment from the algorithm into a new footnote that states “If BRAF/MEK inhibitor combination therapy is contraindicated, BRAF-inhibitor monotherapy with dabrafenib or vemurafenib are recommended options, especially in patients who are not appropriate candidates for checkpoint immunotherapy.”</p>	19	0	0	8
<p><u>ME-G 1 of 6</u> Panel member request: Re-discuss the data and category of evidence for ipilimumab and biochemotherapy for second-line or subsequent treatment of metastatic or unresectable melanoma</p>	<p>Based on a discussion of treatment preferences, panel consensus supported making the following revisions:</p> <ul style="list-style-type: none"> • Changed ipilimumab from category 1 to category 2A • Changed biochemotherapy from category 2B to category 2A 	19	0	0	8
		18	1	0	8