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RE: Submission of Data to the NCCN Melanoma Guidelines Panel for Consideration at the June 20, 2018 Meeting

Submitted by: DermTech, Inc. / Burkhard Jansen, MD
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Date of Request: May 31, 2018 (by June 4 as discussed with Nicole McMillan, MS, Guidelines Coordinator)
NCCN Guidelines Panel: Melanoma (June 20, 2018)

On behalf of DermTech, I respectfully request that the NCCN Melanoma Guidelines Panel review the enclosed data for inclusion of non-invasively obtained gene expression and mutation risk factors to support clinicians in their biopsy decisions and efforts to rule out primary cutaneous melanoma.

To facilitate the review of the data, we provide key details in an attached summary document with hyperlinks to important references.

Specific Changes: Recommend molecular risk factors, ideally assessed non-invasively, be considered to help guide biopsy decisions and rule out primary cutaneous melanomas. Not to be used on clinically frank melanomas or as a screening tool. Useful also when surgical biopsies are not feasible. (Add to ME-A, Page 1, under proposed 'Molecular Risk Factors' header)

Regulatory Clearance: An adhesive patch based non-invasive FDA compliant Class I skin sampling tool is available in the US; it is also Health Canada approved. Molecular pathology melanoma risk factor tests for PRAME and LINC00518 gene expression, for instance, are available through DermTech's CLIA certified, CAP accredited and New York licensed laboratory. Specific Category I 81401 CPT codes for PRAME and LINC00518 became available on January 1, 2018. The code change was supported by 8 specialty societies including the American Academy of Dermatology.

Rationale: Molecular risk factors (including PRAME and LINC00518 gene expression elevated in melanoma and key driver mutations in BRAF, NRAS and the TERT promoter) are known to occur in early melanoma and potentially precede morphological changes that are key to the current standard of care paradigm of visual assessment and histopathologic analysis of pigmented skin lesions suspicious of melanoma. Obtaining validated molecular risk factors of demonstrated utility non-invasively reduces the number needed to biopsy to detect one melanoma from 20-25 to 2.7 and improves the negative predictive value of the current pathway from around 83% to 99% thereby transforming the currently often challenging subjective pathway of pigmented lesion management into an objective one that reduces missed melanomas and cost. Please see attached summary document for data and references.

Sincerely,

Burkhard Jansen, MD