Burkhard Jansen, MD
Chief Medical Officer

11099 N. Torrey Pines Road, Suite 100
La Jolla, CA 92037
Direct: 858.249.9413
Fax: 858.200.3877
www.dermtech.com

June 27, 2019

RE: Submission of Data to the NCCN Cutaneous Melanoma Guidelines Panel for Consideration at the July 21 & 22 2019 Meeting (to Update Guidelines to Version 1.2020)

Submitted by: DermTech, Inc. / Burkhard Jansen, MD
Address: 11099 N. Torrey Pines Road, Suite 100, La Jolla, CA 92037
Phone: 858-249-9413
Email: bjansen@dermtech.com
Date of Request: June 27, 2019 (as also discussed with Nicole McMillan, MS, Guidelines Coordinator)
NCCN Guidelines Panel: Cutaneous Melanoma (July 21 & 22, 2019 for Version 1.2020)

On behalf of DermTech, I respectfully request that the NCCN Cutaneous Melanoma Guidelines Panel review the enclosed Pigmented Lesion Assay (PLA) data for inclusion of non-invasively obtained molecular 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 the attached summary document with hyperlinks to now 14 key peer reviewed manuscripts published in leading dermatology journals that are all fully available and in the public domain. This large body of work from over 4,300 patients and 9 studies includes two separate clinical validation trials, 4 distinct utility studies, an independent health economics study and significant efforts on supporting studies. The most recently published third utility manuscript includes 2 studies with a total of over 2,300 patients. Data sets demonstrate that clinicians change behavior and follow the guidance of the test to surgically biopsy PLA positive lesions and observe PLA negative ones in over 96.5% of cases. There were no missed melanomas in a 12-month follow-up study of 734 PLA negative cases.

We are aware that Version 2.2019 of the current guidelines states that 'the NCCN Guidelines for Cutaneous Melanoma focus on the management of cutaneous melanoma following pathology diagnosis. As such, emerging molecular technologies for pre-diagnostic biopsy purposes (e.g. non-invasive genomic adhesive patch testing) are not within the guidelines' purview.' Only three references are cited in Version 2.2019. Given the progress documented in now 14 provided references that should be cited to eliminate concerns on the emerging nature of the technology and the notion that the Pigmented Lesion Assay has benefited over 30,000 US patients to date by reducing avoidable pigmented lesion biopsies by 90% while improving care with a negative predictive value of over 99% and while reducing cost, we recommend the Specific Changes below:

Specific Changes: 'The NCCN Guidelines for Cutaneous Melanoma generally focus on the management of cutaneous melanoma following pathology diagnosis. However, molecular technologies for pre-diagnostic biopsy purposes (e.g. non-invasive genomic adhesive patch testing) have demonstrated clinical validity and utility and can also be considered to support clinicians in their biopsy decisions.' [1-14]

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 cleared. 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 last year. The code change was supported by 8 specialty societies including the American Academy of Dermatology. A recent positive Draft Local Coverage Determination by MolDX Palmetto (DL38051) proposes coverage utilizing CPT 81479.

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 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. As mentioned above, most recently published additional utility data from a total of over 2,300 patients further support the rationale on the benefits of PLA use for our patients. Data sets demonstrate that clinicians change behavior and follow the guidance of the test to surgically biopsy PLA positive lesions and observe PLA negative lesions in over 96.5% of cases. There were no missed melanomas in a 12-month follow-up study of 734 PLA negative cases. Please see the attached hyperlinked summary document for references and data within these 14 references.

Sincerely,

Burkhard Jansen, MD