DermTech Pigmented Lesion Assay

MOL.TS.282.A
v2.0.2020

Procedures addressed

The inclusion of any procedure code in this table does not imply that the code is under management or requires prior authorization. Refer to the specific Health Plan’s procedure code list for management requirements.

<table>
<thead>
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<th>Procedures addressed by this guideline</th>
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What is melanoma

Definition

According to the American Academy of Dermatology (AAD), the incidence of primary cutaneous melanoma has been increasing substantially for several decades. The incidence of melanoma has been reported to be increasing at a rate of 3% to 7% annually among fair-skinned Caucasian populations, which is faster than other major cancers.¹

Melanoma accounts for the majority of skin cancer related deaths, but treatment is nearly always curative with early detection of disease. Minimal depth (thin) melanomas have a cure rate of nearly 100%, while tumors with a Breslow depth of greater than 4mm have a 10-year survival rate of less than 50%.¹

Standard of care for the assessment of clinically suspicious pigmented skin lesions is surgical biopsy and subsequent histopathology. However, histopathology is believed to have inherent limitations. Some lesions that are likely to be true melanomas based on clinical behavior do not meet the complete set of histologic criteria to establish a melanoma diagnosis.¹ There is also considerable interrater variability with visual image and pattern recognition of skin lesions.² In an effort to improve patient survival, a number of novel noninvasive techniques have been developed to classify pigmented skin lesions at an earlier stage.³
Test information
Introduction

The Pigmented Lesion Assay (PLA) is a non-invasive method for the biopsy of clinically atypical pigmented lesions or moles using an adhesive patch to obtain mRNA from the surface of the suspicious lesion.

According to the manufacturer, the PLA assesses gene expression consistent with melanoma and is intended as a decision making aid for the clinician to determine whether or not to biopsy a pigmented skin lesion, clinically suspicious for melanoma. The test is intended for use on pigmented lesions suspicious for melanoma that meet at least one of the A (asymmetry) B (border) C (color) D (diameter) E (evolving) criteria for which the clinician would like additional information prior to surgical biopsy. Uses of the PLA include the following: lesions being followed for change; lesions in cosmetically sensitive areas of the body; lesions on patients with possible risks for complications during surgical biopsy; or lesions among patients who refuse biopsy.

The PLA is a non-invasive method for the biopsy of clinically atypical pigmented lesions or moles using an adhesive patch to obtain mRNA from the surface of the suspicious lesion. The method of adhesive tape stripping has been used for to obtain RNA from the stratum corneum for gene expression of other disorders, such as allergic and irritant skin reactions and psoriasis. The PLA detects the expression of 2 specific genes, PRAME and LINC00518, both of which are believed to play key roles in oncogenesis and both of which have been shown to be elevated in melanoma. If one or more of the genes is detected by the PLA, the gene expressive is considered positive. The positive lesions generally undergo surgical biopsy to definitively establish a melanoma diagnosis. The test manufacturer notes that this assay cannot be used on mucous membranes, palms of the hands, and soles of the feet.

Guidelines and evidence
Introduction

The following section includes relevant guidelines and evidence pertaining to DermTech PLA.

American Academy of Dermatology (AAD)

The American Academy of Dermatology (AAD) acknowledges that the clinical and prognostic significance of the use of biomarkers and mutational analysis is still unclear and there are gaps regarding their clinical usefulness that have yet to be addressed. The 2019 guideline states: "Routine molecular testing, including GEP, for prognostication is discouraged until better use criteria are defined. The application of molecular information for clinical management (eg, sentinel lymph node eligibility, follow-up, and/or therapeutic choice) is not recommended outside of a clinical study or trial"
Literature review

The evidence is currently insufficient to support the use of the PLA to accurately differentiate melanoma lesions from nonmelanoma lesions.\textsuperscript{1,2,5-9} Study limitations include the small study populations, lack of generalizability of study results to more diverse melanoma subtypes, lack of blinding of primary readers, as well as early reports of insufficient RNA obtained from study samples. Independent prospective clinical utility studies are currently lacking and it is unclear if the use of the PLA versus conventional diagnostic tools leads to changes in health care decision making and improvement in patient survival.

Additional studies

Additional well-designed studies in larger patient populations with diverse melanoma subtypes are needed to add to the evidence base and corroborate the early study findings.

Criteria

Introduction

Requests for DermTech PLA are reviewed using the following criteria.

This test is considered investigational and/or experimental.

- Investigational and experimental (I&E) molecular and genomic (MolGen) tests refer to assays involving chromosomes, DNA, RNA, or gene products that have insufficient data to determine the net health impact, which typically means there is insufficient data to support that a test accurately assesses the outcome of interest (analytical and clinical validity), significantly improves health outcomes (clinical utility), and/or performs better than an existing standard of care medical management option. Such tests are also not generally accepted as standard of care in the evaluation or management of a particular condition.

- In the case of MolGen testing, FDA clearance is not a reliable standard given the number of laboratory developed tests that currently fall outside of FDA oversight and FDA clearance often does not assess clinical utility.

References

Introduction

This guideline cites the following references


