Medicare Local Coverage Determination Policy

MolDX: Pigmented Lesion Assay

CPT: 0089U, ZB6L6

Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

CMS Policy for Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

Medically Supportive ICD Codes are listed on subsequent page(s) of this document.

Coverage Indications, Limitations, and/or Medical Necessity

This Medicare contractor will provide limited coverage for the Pigmented Lesion Assay / PLA (DermTech, Inc., La Jolla, CA), an RNA gene expression test conducted on skin samples obtained non-invasively via adhesive patches.

The PLA is indicated only for use on pigmented skin lesions, for which a diagnosis of melanoma is being considered. **The test may only be ordered by clinicians who evaluate pigmented skin lesions and perform biopsies. The test is covered for use as a source of information on whether or not to perform a biopsy.**

The specific characteristics that the lesion must have are as follows:

- The lesion must meet one or more ABCDE criteria (Asymmetry, Border, Color, Diameter, Evolving)
- Primary melanocytic skin lesions between 5mm and 19mm
- Lesions where the skin is intact (i.e., non-ulcerated or non-bleeding lesions)
- Lesions that do not contain a scar or were previously biopsied
- Lesions not located in areas of psoriasis, eczema or similar skin conditions
- Lesions not already clinically diagnosed as melanoma or for which the clinical suspicion is sufficiently high that the treating clinician believes melanoma is a more likely diagnosis than not
- Lesions in areas other than palms of hands, soles of feet, nails, mucous membranes and hair covered areas that cannot be trimmed

Additional coverage requirements:

- The ordering clinician must also have a plan at the time of ordering the test to continue to monitor the skin lesion for changes if the test is negative. **The record must also contain a photograph of the lesion at the time that the PLA is ordered to allow for appropriate evaluation in subsequent follow-up.**
- **Records must clearly support that the ordering clinician has the knowledge, skills, and experience to evaluate and biopsy pigmented skin lesions. If this information is not contained with the chart of the beneficiary to whom a service is being rendered, it must be supported by other readily available documentation, such as credentialing documentation, or documentation of training in the performance of such tasks. Such documentation should be provided if there are documentation requests.**
- The ordering physician must clearly document the lesion site on the patient's body
- The test may not be ordered for the same lesion a second time.
- Only one test may be used per patient per clinical encounter in most cases. **In roughly 10% of patients, a second test may be indicated for the same clinical encounter. For rare cases where more than 2 tests are indicated in a single clinical encounter, an appeal with supporting documentation may be submitted for additional tests.**

The PLA is not intended to be used as a screening test in patients without melanocytic skin lesions. It is also not covered as an adjunctive test in lesions that are considered to already warrant a biopsy. The PLA is a decision tool for atypical melanocytic lesions prior to the decision to biopsy.

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Specific Coverage Criteria

The Pigmented Lesion Assay (PLA) is indicated for use on melanocytic skin lesions with one or more clinical or historical characteristics suggestive of melanoma, including one or more ABCDE criteria (Asymmetry, Border, Color, Diameter, Evolving) when a clinician trained in the clinical diagnosis of skin cancer is considering the need for biopsy to rule out melanoma. The PLA should not be used on clinically obvious melanoma. The PLA result is one element of the overall clinical assessment and should be used in combination with clinical and historical signs of melanoma to obtain additional information prior to a decision to biopsy.

(PLA positive lesions (LINC and/or PRAME detected) should be considered for biopsy. The biopsy decision of a PLA negative lesion should be based on the remainder of the entire clinical context.)

The PLA is indicated only for use on:
- Primary melanocytic skin lesions between 5mm and 19mm
- Lesions where the skin is intact (i.e. non-ulcerated or non-bleeding lesions)
- Lesions that do not contain a scar or were previously biopsied
- Lesions not located in areas of psoriasis, eczema or similar skin conditions
- Lesions not clinically diagnosed as melanoma
- Lesions in areas other than palms of hands, soles of feet, nails, mucous membranes and hair covered areas that cannot be trimmed

The PLA is not intended to be used as a screening test in patients without melanocytic skin lesions. It is also not covered as an adjunctive test in lesions that are considered to already warrant a biopsy. The PLA is a decision tool for atypical melanocytic lesions prior to the decision to biopsy.

The evaluation with the PLA is limited to order by a physician or other qualified healthcare professional.

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Please refer to the Limitations or Utilization Guidelines section on previous page(s) for frequency information.

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. **If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.**

Code	Description
D48.5	Neoplasm of uncertain behavior of skin

Visit **SonoraQuest.com/Medicare** to view current limited coverage tests, reference guides, and policy information.

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference CMS Website ►

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