Local Coverage Determination (LCD): MolDX: myPath Melanoma Assay (L37881)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

LCD Information

Document Information

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L37881

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LCD Title

Revision Effective Date

MolDX: myPath Melanoma Assay

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Proposed LCD in Comment Period
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AMA CPT / ADA CDT / AHA NUBC Copyright Statement

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CMS National Coverage Policy

Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A), states that no Medicare payment shall be made for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

Title XVIII of the Social Security Act, §1833(e), prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.

42 Code of Federal Regulations (CFR) §410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

CMS On-Line Manual, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, §§80.0, 80.1.1, 80.2. Clinical Laboratory services.

CMS Internet-Only Manuals, Publication 100-04, Medicare Claims Processing Manual, Ch. 16, §50.5 Jurisdiction of Laboratory Claims, §60.12 Independent Laboratory Specimen Drawing, §60.2. Travel Allowance.

CMS Internet Online Manual Pub. 100-04 (Medicare Claims Processing Manual), Chapter 23 (Section 10) "Reporting ICD Diagnosis and Procedure Codes".

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

The purpose of this test is to assist dermatopathologists to properly and accurately diagnose the melanomas versus the non-melanomas when examining skin biopsies.

This Medicare contractor will provide limited coverage for the myPath Melanoma assay (Myriad Genetic Laboratories, Salt Lake City, UT; Z-Code ZB041) for the diagnosis or exclusion of melanoma from a biopsy when all of the following clinical conditions are met:

- The test is ordered by a board-certified dermatopathologist and;
- The specimen is a primary cutaneous melanocytic neoplasm for which the diagnosis is equivocal / uncertain (i.e. clear distinction between benign or malignant cannot be achieved using clinical and / or histopathological features alone) and;
- The patient may be subjected to additional intervention, such as re-excision and/or sentinel lymph node biopsy, as a result of the diagnostic uncertainty.

Summary of Evidence

Melanoma is an aggressive cancer with an estimated 87,110 cases and 9,730 deaths in 2017. The lifetime risk of developing melanoma in the United States is now 1 in 34 for men and 1 in 54 for women.[1] However, many melanomas are curable if detected early and diagnosed accurately. The ten year survival rate for patients with stage I melanomas is 86-95%, compared with only 10-15% among patients with stage IV melanomas.[2]

Melanoma can be difficult to diagnose, particularly in its earliest stages, yet accurate diagnosis of melanocytic neoplasms is vital to optimal patient outcomes. Histopathologic examination has long been the gold standard for melanoma diagnosis, and while it is adequate for most cases, evidence suggests that approximately 15% of all biopsied melanocytic neoplasms are difficult to diagnose by histopathology alone.[3,4] Even experienced dermatopathologists disagree in some cases, and, depending on the type of lesions evaluated, diagnostic discordance may be substantial.[5,6] In equivocal cases, patients may receive diagnoses that are indeterminate or inaccurate, leading to inappropriate treatment. Unnecessary re-excisions, sentinel lymph node biopsies, and protracted clinical follow-up may result when a diagnostically challenging benign lesion is reported as indeterminate.[7,8] Conversely, a diagnostically challenging melanoma mistakenly classified as a benign nevus may result in under-treatment and subsequent progression to late-stage melanoma.[7,8] Consequently, adjuncts to histopathology have been sought in efforts to improve diagnostic accuracy in equivocal cases.

Test Description and Intended Use

The Myriad myPath Melanoma assay is a 23-gene expression signature developed to provide an objective, reproducible, and accurate adjunctive method for differentiating malignant melanoma from benign nevi.[9-12] The test is intended for use by dermatopathologists confronting primary cutaneous melanocytic neoplasms for which the diagnosis of malignant melanoma versus benign nevus is equivocal / uncertain (i.e. a clear distinction between benign or malignant cannot be achieved using clinical and / or histopathological features alone). Use of the test in these cases increases definitive diagnoses, and evidence suggests it may reduce unnecessary procedures in benign lesions.[13,14]

The myPath Melanoma test quantifies the expression of 23 genes by quantitative RT-PCR. Fourteen of the 23 genes are known to be over-expressed by malignant melanomas relative to benign nevi. The remaining nine are stably expressed reference genes which allow correction for sample-to-sample variations in RT-PCR efficiency and errors in sample quantification (normalization). The signature genes represent three distinct pathways that contribute to melanoma pathogenesis, including aspects of melanocyte differentiation as well as characteristics of the tumor microenvironment such as cell-cell signaling and tumor-induced host immune responses.[9,10] The test uses five to seven standard-thickness (4-5 μm) sections taken from the routinely processed formalin-fixed paraffin-embedded (FFPE) tissue of the existing biopsy specimen, allowing its integration into routine clinical practice and its use even in small, early-stage lesions.

The quantified expression of all 23 genes is combined algorithmically and reported as a single numerical score. That number (the myPath Melanoma 'score'), is plotted on a scale that depicts the entire range of scores observed in clinical validation studies.[10] Physicians receive a report showing this single numerical score and the corresponding classification: 'likely malignant', 'likely benign', or 'indeterminate'.

Analytical Validation

This assay's analytical validation is consistent with industry standards and existing MolDX criteria (see Summary of Analytical Performance, below).[9]

Clinical Validation

Histopathology can accurately classify many melanocytic neoplasms and currently serves as the 'gold' standard for the diagnosis of melanoma. In line with standard practice, therefore, adjunctive molecular tests for melanoma diagnosis have largely been developed and initially evaluated using histopathology as the reference standard. The first two validation studies of myPath Melanoma test demonstrated greater than 90% diagnostic accuracy by comparison to concordant histopathologic diagnoses (diagnoses arrived at independently by multiple expert dermatopathologists).[10,11] To further assess accuracy using a reference standard independent of histopathologic diagnosis and confirm genuine clinical utility, a third clinical validation study was performed in which the test result was compared to the eventual clinical outcomes of tested patients.[12] In a cohort of 182 melanocytic neoplasms collected from patients with documented outcomes (distant metastases for malignant melanomas and median 6+ year uneventful follow-up for benign nevi), the myPath Melanoma score differentiated malignant melanoma from benign nevi with a sensitivity of 93.8% and a specificity of 96.2%.12

As shown below, these studies collectively demonstrate the ability of myPath Melanoma to accurately differentiate malignant melanoma from benign nevi.

Summary of Clinical Validation Studies for the myPath Melanoma Assay

Study	Design	Population	N	Sensitivity	Specificity
Clarke et al 2015 *Journal of Cutaneous Pathology*[10]	Archival, Retrospective	Diverse cohort of archival melanocytic neoplasms	437	90%	91%
Clarke et al 2016 *Cancer*[11]	Prospective	Diverse cohort of prospectively submitted contemporary melanocytic neoplasms	736	92%	93%
Ko et al 2017 *Cancer Biomarkers, Epidemiology, & Prenvention*[12]	Archival, Retrospective	Melanocytic neoplasms with diagnoses proven by clinical outcome data	182	94%	96%

Clinical Utility

Two separate clinical utility studies have quantified the clinical impact of the myPath Melanoma score.[13,14] The first calculated the test's effect on dermatopathologists and their diagnostic reports, while the second evaluated the impact of the test on dermatologists receiving those reports and the actual treatment provided to tested patients.

The first clinical utility study[13] quantified the influence of the myPath Melanoma score on both the final diagnoses and the treatment recommendations made by board-certified dermatopathologists for 218 prospectively-submitted diagnostically challenging (equivocal or uncertain) melanocytic neoplasms encountered during routine clinical practice. Comparison of pre-test and post-test diagnoses demonstrated a 56% increase in definitive diagnoses with use of the myPath score (a 30% increase in definitive diagnoses of benign nevus and a 12.4% increase in definitive diagnoses of malignant melanoma). In addition, treatment recommendations provided by dermatopathologists changed for 49% of patients after receiving the myPath result, with 76.6% of those changes aligned to the test result.[13]

The second clinical utility study[14] assessed the relationship between test result and change in treatment as measured by pretest dermatopathologist recommendation and posttest actual treatment delivered to a patient by the dermatologist. A cohort of 77 patients with pretest diagnoses of "indeterminate" (equivocal, uncertain) were followed throughout their clinical course. The myPath test produced definitive scores for all 77 neoplasms, and after a median 12-month follow-up period, the tested patients' dermatologists disclosed the actual treatment carried out in each case. The treatment differed from the pretest recommendation in 55 of 77 (71.4%) cases, 44 of which produced a benign myPath test result. Re-excision was the pretest treatment recommendation for 41 of these 44 cases, yet re-excision was ultimately performed in just 7, indicating that a benign myPath test result enabled dermatologists to forego further intervention in 33 of the 41 cases, yielding an 80.5% reduction in re-excisions.[14]

Taken together, the clinical utility studies demonstrate that Medicare beneficiaries with diagnostically challenging primary cutaneous melanocytic neoplasms tested with myPath Melanoma will have improved outcomes by comparison to untested patients, as defined by an increase in accurate diagnoses[13] and a reduction in burdensome and unnecessary treatments.[14] Evidence supports accuracy of the myPath Melanoma test by correlation to long-term clinical outcomes.[12]

Recently, the Association for Molecular Pathology (AMP) recognized that "accurate diagnosis has inherent clinical utility and is foundational to directing patient care to improve clinical outcomes."[15] In light of this, the finding of Cockerell et al[13] that 57.3% of patients with indeterminate pre-test diagnoses received definitive diagnoses after myPath Melanoma testing has significant clinical utility, in that tested patients receive more accurate diagnostic information on which to base treatment decisions by comparison to untested patients. The demonstrated net outcome among patients with benign myPath test results and a change in treatment was an 80.5% reduction in unnecessary re-excisions.[14]

Other diagnostic adjuncts for melanocytic neoplasms rely upon the detection of chromosomal aberrations within neoplastic melanocytes (tumor cytogenetics) and include fluorescence in situ hybridization (FISH)[16-21] and aCGH / SNP array.[16, 22-25] FISH queries four to six chromosomal loci through hybridization of fluorescent probes. Tissue requirements are minimal (25-35 μm),[16] and since FISH involves visualization of the tissue, aberrations may be detected within tumor cell subpopulations. Melanomas lacking aberrations at the 4-6 target loci will be undetected, however, generating false negative results,[17-21] while polyploidy may produce false positives[20,21] (but may be detected by experienced observers). Results are uninterpretable (e.g. insufficient signal) in 5-30% of cases.[17-19] Probe sets, cut-off thresholds, and observer skill and experience vary among laboratories, and inter-observer variability occurs.[20,21,25]

In contrast to FISH, SNP array / aCGH methodologies interrogate the genome more broadly[22-25] and signal quantification does not involve human interpretation. However, tumors must be relatively homogenous (~40%),24 meaning that aberrations in cell subpopulations may go undetected. The large quantity of tissue required (125-375 μm / 10 mm2)[16] restricts use to thicker tumors, and the significance of some aberrations remains unknown.

By comparison to the cytogenetic techniques, the myPath test quantifies the RNA transcripts produced by 14 genes over-expressed in malignant melanoma.[9-12] Human interpretation is not involved, maximizing objectivity and reproducibility (2.5% SD).[9] Testing is performed in a single laboratory, reducing variation in methods and reagents, and tissue requirements are minimal (25-35 μm, similar to FISH).9 However, testing requires an area in which neoplastic melanocytes represent approximately 10% of the specimen,[9-11] and scores between -2.0 and -0.1 are classified as indeterminate (9% of tested cases). The assay is only validated for primary cutaneous neoplasms, precluding testing of metastases, non-cutaneous melanomas, and re-excision specimens.[9-12]

National Clinical Guidelines

The National Comprehensive Cancer Network (NCCN) Melanoma Panel updated the 2018 Melanoma Guidelines 'Principles of Pathology' to reflect inclusion of diagnostic gene expression tests such as myPath Melanoma as adjuncts to be considered for histologically equivocal lesions.[26]

Summary of Analytical Performance

General

Intended Use Population	The myPath Melanoma assay has been developed and validated to differentiate malignant melanoma from benign melanocytic nevi in primary cutaneous melanocytic neoplasms for which the diagnosis is equivocal / uncertain (i.e. a clear distinction between benign or malignant cannot be achieved using clinical and / or histopathological features alone). Specimens for testing must include an area representative of the lesion or portion of the lesion that is suspicious for malignancy.
Validated Specimen Types	The assay is designed for use with formalin-fixed, paraffin-embedded (FFPE) sections representative of the primary cutaneous melanocytic neoplasm.

Analytical Performance

Parameter	**Result** (w/ 95% confidence intervals where applicable)
Repeatability (Intra-assay)	Repeatability (i.e. intra-assay) was demonstrated by performing three replicate measurements for multiple samples, the error of which is included within the intermediate precision estimation, below.[9]
Intermediate Precision (Inter-assay)	Intermediate (i.e. inter-batch, inter-assay) precision was determined by analyzing multiple specimens with three replicate measurements for each sample (starting from tissue sections for each replicate measurement). The standard deviation of the overall score was determined to be 0.7 score units for both the TLDA and OpenArray platforms, which corresponds to 2.5% of the total range of observed / reportable molecular scores.[9,10] These estimates include error attributable to the use of multiple instruments, technicians, and reagent lots, and samples run on different days.
Reproducibility	N/A (this test is performed in only one laboratory)
Lot-to-lot Reproducibility	Included within the intermediate precision estimations, where multiple

	reagent lots, technicians, and instruments were used.
Limit of Detection	In an assessment of the linear range of the RNA concentration, the lowest RNA concentrations that generated scores within the linear range for the TLDA and OpenArray platforms were 0.5 ng/µL and 1.0 ng/µL, respectively.[9]
Limits of Quantitation (Upper and Lower)	For RNA input, the linear ranges for RNA concentration are 0.5 to 1000 ng/µL for the TLDA platform and 1.0 to 500 ng/µL for the OpenArray platform.[9] Clinical testing is restricted to samples with RNA concentrations between 2 and 40 ng/ µL. Samples with concentrations <2 ng/µL are not tested (due to limitations of RNA quantitation) and samples >40 ng/µL are diluted to 40 ng/µL.[9]
Linearity and Reportable Range	For RNA input, the linear range for the RNA concentration is 0.5 to 1000 ng/µL for the TLDA platform and 1.0 to 500 ng/µL on the OpenArray platform.[9] The cohort of samples tested in the first clinical validation study produced scores ranging from -16.7 to 11.1. This was established as the reportable range.[10] Scores outside of this range are not reported.
Minimum Input Quantity and Quality	The minimum RNA concentration is 2 ng/µL (25 ng of total RNA), which was established by the limit of RNA quantitation (UV spectrophotometry) and not by the linear range of RNA input [9]
Minimum Tumor Content	The smallest testable neoplasm is 0.125 millimeters.[9,10] Minimum tumor content is 10%.[9-11]
Primer and Probe Specificity	The TaqMan primers and probe sequences are not disclosed by ThermoFisher Scientific. The complete list of TaqMan assays comprising the signature is included within the analytical validation publication.[9]
Interfering Substances	Melanin interference with quantitative PCR occurred at concentrations >0.5 µg/µL (exogenous melanin added to extracted RNA in increasing concentrations). However, it was observed that the RNA extraction process eliminates melanin of quantities sufficient to interfere with testing.[9]

Analysis of Evidence
(Rationale for Determination)

Level of Evidence

Quality – Moderate
Strength – Moderate
Weight - Limited

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type.Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

CODE	DESCRIPTION
81479	UNLISTED MOLECULAR PATHOLOGY PROCEDURE

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
D22.0	Melanocytic nevi of lip

ICD-10 CODE	DESCRIPTION
D22.10	Melanocytic nevi of unspecified eyelid, including canthus
D22.111	Melanocytic nevi of right upper eyelid, including canthus
D22.112	Melanocytic nevi of right lower eyelid, including canthus
D22.121	Melanocytic nevi of left upper eyelid, including canthus
D22.122	Melanocytic nevi of left lower eyelid, including canthus
D22.20	Melanocytic nevi of unspecified ear and external auricular canal
D22.21	Melanocytic nevi of right ear and external auricular canal
D22.22	Melanocytic nevi of left ear and external auricular canal
D22.30	Melanocytic nevi of unspecified part of face
D22.39	Melanocytic nevi of other parts of face
D22.4	Melanocytic nevi of scalp and neck
D22.5	Melanocytic nevi of trunk
D22.60	Melanocytic nevi of unspecified upper limb, including shoulder
D22.61	Melanocytic nevi of right upper limb, including shoulder
D22.62	Melanocytic nevi of left upper limb, including shoulder
D22.70	Melanocytic nevi of unspecified lower limb, including hip
D22.71	Melanocytic nevi of right lower limb, including hip
D22.72	Melanocytic nevi of left lower limb, including hip
D22.9	Melanocytic nevi, unspecified
D48.5	Neoplasm of uncertain behavior of skin
D49.2	Neoplasm of unspecified behavior of bone, soft tissue, and skin

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

N/A

General Information

Associated Information

N/A

Sources of Information

N/A

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Revision History Information

N/A

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A56388 - Response to Comments: MolDX: myPath Melanoma Assay

LCD(s)

DL37881 - MolDX: myPath Melanoma Assay

Related National Coverage Documents

N/A

Public Version(s)

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