Local Coverage Determination (LCD): MolDX: myPath Melanoma Assay (L37879)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
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LCD Information

Document Information

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L37879

LCD Title
MolDX: myPath Melanoma Assay

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."

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

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

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, & Prevention*[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

General Information

Associated Information

N/A

Sources of Information

N/A

Bibliography

1. American Cancer Society. Cancer Facts & Figures 2017. Available at https://www.cancer.org/cancer/melanoma-skin-cancer/about/key-statistics.html. Accessed 1/2017.
2. American Cancer Society. What are the survival rates for melanoma skin cancer by stage? Available at https://www.cancer.org/cancer/melanoma-skin-cancer/detection-diagnosis-staging/survival-rates-for-melanoma-skin-cancer-by-stage.html 2017.
3. Shoo BA, Sagebiel RW , Kashani-Sabet M. Discordance in the histopathologic diagnosis of melanoma at a melanoma referral center. J Am Acad Dermatol. 2010;62:751-6.
4. Veenhuizen KC, De Wit PE, Mooi WJ, Scheffer E, Verbeek AL , Ruiter DJ. Quality assessment by expert opinion in melanoma pathology: experience of the pathology panel of the Dutch Melanoma Working Party. The Journal of Pathology. 1997;182:266-72.
5. Farmer ER, Gonin R, Hanna MP. Discordance in the histopathologic diagnosis of melanoma and melanocytic nevi between expert pathologists. Hum Pathol. 1996 Jun;27(6):528-31.
6. Cerroni L, Barnhill R, Elder D, Gottlieb G, Heenan P, Kutzner H, LeBoit PE, Mihm M Jr, Rosai J, Kerl H. Melanocytic tumors of uncertain malignant potential: results of a tutorial held at the XXIX Symposium of the International Society of Dermatopathology in Graz, October 2008. Am J Surg Pathol. 2010 Mar;34(3):314-26.
7. Hawryluk EB, Sober AJ, Piris A, Nazarian RM, Hoang MP, Tsao H et al. Histologically challenging melanocytic tumors referred to a tertiary care pigmented lesion clinic. J Am Acad Dermatol. 2012;67:727-35.
8. McGinnis KS, Lessin SR, Elder DE, Guerry Dt, Schuchter L, Ming M et al. Pathology review of cases presenting to a multidisciplinary pigmented lesion clinic. Archives of Dermatology 2002;138:617-21.
9. Warf MB, et al. Analytical validation of a melanoma diagnostic gene signature using formalin-fixed paraffin-embedded melanocytic lesions. Biomark Med 2015; 9:407-16.
10. Clarke LE, Warf MB, Flake DD 2nd, Hartman AR, Tahan S, Shea CR, Gerami P, Messina J, Florell SR, Wenstrup RJ, Rushton K, Roundy KM, Rock C, Roa B, Kolquist KA, Gutin A, Billings S, Leachman S. Clinical validation of a gene expression signature that differentiates benign nevi from malignant melanoma. J Cutan Pathol. 2015 Apr;42(4):244-52.
11. Clarke LE, Flake DD 2nd, Busam K, Cockerell C, Helm K, McNiff J, Reed J, Tschen J, Kim J, Barnhill R, Elenitsas R, Prieto VG, Nelson J, Kimbrell H, Kolquist KA, Brown KL, Warf MB, Roa BB, Wenstrup RJ. An Independent Validation of a Gene Expression Signature to Differentiate Malignant Melanoma from Benign Melanocytic Nevi. Cancer 2016 Oct 21.
12. Ko JS, Matharoo-Ball B, Billings SD, Thomson BJ, Tang JY, Sarin KY, Cai E, Kim J, Rock C, Kimbrell HZ, Flake DD 2nd, Warf MB, Nelson J, Davis T, Miller C, Rushton K, Hartman AR, Wenstrup RJ, Clarke LE. Diagnostic Distinction of Malignant Melanoma and Benign Nevi by a Gene Expression Signature and Correlation to Clinical Outcomes. Cancer Epidemiol Biomarkers Prev. 2017 Jul;26(7):1107-1113.
13. Cockerell CJ, Tschen J, Evans B, Bess E, Kidd J, Kolquist KA, Rock, C, Clarke LE. The Influence of a Gene Expression Signature on the Diagnosis and Recommended Treatment of Melanocytic Tumors by

Dermatopathologists. Medicine 2016; 95(40):e4887.
14. Cockerell CJ, Tschen J, Billings SD, Evans B, Brown K, Rock C, and Clarke LE. The influence of a gene-expression signature on the treatment of diagnostically challenging melanocytic lesions. Per Med 2017; 14(2), 123–130
15. Joseph L, Cankovic M, Caughron S, Chandra P, Emmadi R, Hagenkord J, Hallam S, Jewell KE, Klein RD9 Pratt VM, Rothberg PG, Temple-Smolkin RL, Lyon E. The Spectrum of Clinical Utilities in Molecular Pathology Testing Procedures for Inherited Conditions and Cancer: A Report of the Association for Molecular Pathology. J Mol Diagn. 2016 Sep;18(5):605-619.
16. North JP, Vemula SS, Bastian BC. Molecular Diagnostics for Melanoma: Methods and Protocols, in Methods in Molecular Biology, vol. 1102, Thurin and Marincola (eds), Springer Science+Business Media, New York, 2014.
17. Díaz A, Valera A, Carrera C, Hakim S, Aguilera P, García A, Palou J, Puig S, Malvehy J, Alos L. Pigmented spindle cell nevus: clues for differentiating it from spindle cell malignant melanoma. A comprehensive survey including clinicopathologic, immunohistochemical, and FISH studies. Am J Surg Pathol. 2011 Nov;35(11):1733-42.
18. Abásolo A1, Vargas MT, Ríos-Martín JJ, Trigo I, Arjona A, González-Cámpora R. Application of fluorescence in situ hybridization as a diagnostic tool in melanocytic lesions, using paraffin wax-embedded tissues and imprint-cytology specimens. Clin Exp Dermatol. 2012 Dec;37(8):838-43.
19. Clemente C, Bettio D, Venci A, Scopsi L, Rao S, Ferrari A, Piris A, Mihm MC Jr. A fluorescence in situ hybridization (FISH) procedure to assist in differentiating benign from malignant melanocytic lesions. Pathologica. 2009 Oct;101(5):169-74.
20. Gerami P, Jewell SS, Morrison LE, Blondin B, Schulz J, Ruffalo T, Matushek P 4th, Legator M, Jacobson K, Dalton SR, Charzan S, Kolaitis NA, Guitart J, Lertsbarapa T, Boone S, LeBoit PE, Bastian BC. Fluorescence in situ hybridization (FISH) as an ancillary diagnostic tool in the diagnosis of melanoma. Am J Surg Pathol. 2009 Aug;33(8):1146-56.
21. Gerami P, Li G, Pouryazdanparast P, Blondin B, Beilfuss B, Slenk C, Du J, Guitart J, Jewell S, Pestova K. A highly specific and discriminatory FISH assay for distinguishing between benign and malignant melanocytic neoplasms. Am J Surg Pathol. 2012 Jun;36(6):808-17.
22. Bastian BC, LeBoit PE, Hamm H, Bröcker EB, Pinkel D Chromosomal gains and losses in primary cutaneous melanomas detected by comparative genomic hybridization. Cancer Res. 1998 May 15;58(10):2170-5.
23. Bastian BC, Olshen AB, LeBoit PE, Pinkel D. Am J Pathol. Classifying melanocytic tumors based on DNA copy number changes. 2003 Nov;163(5):1765-70.
24. Wang L, Rao M, Fang Y, Hameed M, Viale A, Busam K, Jhanwar SC. A genome-wide high-resolution array-CGH analysis of cutaneous melanoma and comparison of array-CGH to FISH in diagnostic evaluation. J Mol Diagn. 2013 Sep;15(5):581-91.
25. Gaiser T, Kutzner H, Palmedo G, Siegelin MD, Wiesner T, Bruckner T, Hartschuh W, Enk AH, Becker MR. Classifying ambiguous melanocytic lesions with FISH and correlation with clinical long-term follow up. Mod Pathol. 2010 Mar;23(3):413-9.
26. National Comprehensive Cancer Network. NCCN.org. NCCN Clinical Practice Guidelines in Oncology – Melanoma. Version 2.2018, Updated January 19, 2018; accessed May 15, 2018. https://www.nccn.org/professionals/physician_gls/pdf/melanoma.pdf

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
11/01/2019	R3	The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.	• Other (The LCD is revised to remove CPT/HCPCS

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	codes in the Keyword Section of the LCD.)
11/01/2019	R2	11/01/2019: This LCD is being revised in order to adhere to CMS requirements per chapter 13, section 13.5.1 of the Program Integrity Manual. Regulations regarding billing and coding were removed from the **CMS National Coverage Policy** section of this LCD and placed in the related Billing and Coding: myPath Melanoma Assay Article A57626.	• Provider Education/Guidance
11/01/2019	R1	11/1/19: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage. As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD.	• Provider Education/Guidance • Revisions Due To Code Removal

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)
A57626 - Billing and Coding: MolDX: myPath Melanoma Assay
A56387 - Response to Comments: MolDX: myPath Melanoma Assay
LCD(s)
DL37879 - MolDX: myPath Melanoma Assay

Related National Coverage Documents

N/A

Public Version(s)

Updated on 01/29/2020 with effective dates 11/01/2019 - N/A

Updated on 12/17/2019 with effective dates 11/01/2019 - N/A
Updated on 10/25/2019 with effective dates 11/01/2019 - N/A
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Keywords

N/A