PRESBYTERIAN

Medical Policy

Subject: Genetic Testing for Cutaneous Melanoma

Medical Policy #: 7.7 **Original Effective Date:** 09/25/2019

Status: Reviewed **Last Annual Review Date:** 08/27/2025

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans, or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

"The DecisionDx-Melanoma test is a 31-gene expression profile (GEP) that determines a CM patient's risk for metastatic disease. The test classifies patients as having a tumor with low (Class 1) or high (Class 2) risk for developing metastasis within 5 years of diagnosis. Patients with a Class 1 tumor profile also have a low likelihood of being sentinel lymph node (SLN) positive. Thus, the individualized risk profile result of this test can be used to guide use of SLNB in the context of patient-specific management plans."

MyPath Melanoma is a gene expression profiling (GEP) test intended for the suspicious skin lesion and/or cutaneous melanocytic lesions for which malignant potential is uncertain and initial biopsy is indeterminate for the diagnosis of melanoma.

Pigmented Lesion Assay (PLA) by DermTech is a proprietary non-invasive adhesive patch biopsy genetic test. The test helps dermatologists rule out melanoma and the need for surgical biopsy of atypical, pigmented lesions, melanocytic in origin, with a suspicion for melanoma.

Determination

Prior Authorization is required. Logon to Pres Online to submit a request:
https://ds.phs.org/preslogin/index.jsp

Covered Services:

1. **myPath Melanoma (0090U):**

   Medicare and Medicaid.

   PHP follows WPS, Molecular Assays for the Diagnosis of Cutaneous Melanoma (L39479), LCA (A59261), This test is for diagnostic test for neoplasm of uncertain behavior of the lip or skin.

   Non-covered Commercial:

   PHP follows National Comprehensive Cancer Network (NCCN) and/or MCG A-0837, that testing with GEP is considered experimental, investigational, or unproven and therefore not covered.

2. **DecisionDx® DiffDx™- Melanoma (0314U):**

   Medicare and Medicaid.

   PHP follows WPS, Molecular Assays for the Diagnosis of Cutaneous Melanoma (L39479), LCA (A59261). This test is for diagnostic test for neoplasm of uncertain behavior of the lip or skin.

   Non-covered for Commercial:

   PHP follows National Comprehensive Cancer Network (NCCN) and/or MCG A-0837, that testing with GEP is considered experimental, investigational, or unproven and therefore not covered.

3. **Pigmented Lesion Assay (PLA) by DermTech (0089U):**

Medicare and Medicaid.

PHP follows WPS, Molecular Assays for the Diagnosis of Cutaneous Melanoma (L38178), LCA (A57983. The PLA is indicated only for use on pigmented skin lesions, for which a diagnosis of melanoma is being considered.

Non-covered for Commercial.
PHP follows National Comprehensive Cancer Network (NCCN) and/or MCG A-0837, that testing with PLA is considered experimental, investigational, or unproven and therefore non-covered.

PHP follows National Comprehensive Cancer Network (NCCN) and/or MCG A-0837, that testing with GEP is considered experimental, investigational, or unproven and therefore non-covered.

4. **DecisionDx Melanoma (81529):**

Medicare and Medicaid.

PHP follows WPS, MolDX: Melanoma Risk Stratification Molecular Testing, (L38018), related LCA (A56636) **or** other outside region LCD issued by the A/B MAC that enrolled the provider and processes all of the Medicare claims for that item or service.

As of current, PHP considers DecisionDx-Melanoma test, a 31-gene expression tumor tissue profile test to be a *performance characteristic equivalent or superior to other similar* molecular diagnostic tests used to assist in risk stratification of melanoma.

"Based on the evidence published and reviewed to date, this payor sees evidence that GEP testing may be used to better risk stratify and manage melanoma patients as defined in the coverage section of the LCD policy. The data supporting this test is limited and imperfect; however, the current alternative tools for assessing patient risk stratification in this population in accepted practice are even more so; with this policy we leave it to clinicians to use these services to mitigate a challenging clinical situation and hope that further evidence is developed to clearly guide melanoma patient management. We await more comprehensive published and peer-reviewed prospective data that support or refute changes in patient management based on the use of these or other similar tests. Since the clinical utility of testing is dependent upon consensus-based management recommendations based on risk, this coverage decision is subject to change pending changes in the consensus recommended use of risk strata for patient management and the accuracy of alternative risk-stratification tools. This coverage decision will be periodically re-evaluated."

Non-covered for Commercial:

PHP follows, MCG (A-0837), Melanoma (Cutaneous Gene Expression Profiling and/or NCCN, that testing with GEP is considered experimental, investigational, or unproven and therefore not covered.

Note: Predictive GEP tests to differentiate melanomas at low versus high risk for nodal metastasis should not replace surgical oncology discussion of pathologic staging procedures and are not recommended outside of the context of a clinical study or trial.

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	Description
81529	Oncology (cutaneous melanoma), mRNA, **gene expression profiling** by real-time RT-PCR of 31 genes (28 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk, including likelihood of sentinel lymph node metastasis. e.g. DecisionDX Melanoma
0089U	Oncology (melanoma), **gene expression profiling** by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es) Pigmented Lesion Assay (DermTech Melanoma Test)

CPT Codes	Description
0090U	Oncology (cutaneous melanoma), mRNA **gene expression profiling** by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant) myPath® Melanoma
0314U	Oncology (cutaneous melanoma), mRNA **gene expression profiling** by RT-PCR of 35 genes (32 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant) DecisionDx® DiffDx™- Melanoma

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee (PHCQC): Clinton White MD
Senior Medical Director: Jim Romero MD
Medical Director: Kresta Antillon MD
Date Approved: 08-27-2025

References

1. CMS, Novitas, Genetic Testing for Oncology, LCD L39365, effective date 07/17/2023. [Cited 02/05/2025]
2. CMS, Novitas, Billing and Coding: Genetic Testing for Oncology, LCA (A59125), Effective date:07/17/2023. [Cited 07/08/2025]
3. CMS, Local Coverage Determination, MolDX: DecisionDX-Melanoma (L38018), Wisconsin, J-05, Effective Date 08/12/2019, Revision date: 06/20/2024, R#5. [Cited 07/08/2025]
4. CMS, Local Coverage Article, Billing and Coding for MolDX: DecisionDX-Melanoma (A56636), Effective date 08/12/2019, Revised Date: 07/03/2022, R#7. [Cited 07/08/2025]
5. CMS, Local Coverage Determination, MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma (L39479), Updated on 06/22/2023 [Cited 07/08/2025]
6. CMS, Local Coverage Determination, MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma, (A59261), revision date 08/13/2023 R1 [Cited 07/08/2025]
7. CMS, Wisconsin, (New Mexico Part A), MolDX Pigmented Lesion Assay, LCD (L38178), revision date: 12/2023. Companion article LCA (A57983), Revision Date: 12/2023. [Cited 07/08/2025]
8. National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2025 —Jan 28, 2025, Cutaneous Melanoma, [Cited 07/08/2025]
9. Hayes, DecisionDX-Melanoma, Molecular Test Assessment Mar 29, 2022, Annual Review: Feb 27, 2024, SOMATIC. [Cited 07/08/2025]
10. MCG, Melanoma (Cutaneous) - Gene Expression Profiling, A-0837, Ambulatory Care 29th Edition, Last Update: 1/25/2025 [Cited 07/08/2025]
11. Hayes, myPath Melanoma (Castle Biosciences Inc.), Precision Medicine Research Brief, Jun 27, 2023 | SOMATIC. [Cited 07/08/2025]
12. UpToDate, Tumor, node, metastasis (TNM) staging system and other prognostic factors in cutaneous melanoma, Literature review current through: Jun 2025. This topic last updated: May 09, 2025. [Cited 07/08/2025]
13. Aetna, Tumor Markers, #0352, Last review: 04/02/2025, Next review:04/10/2025. [Cited 07/08/2025]
    Aetna, Total Body Photography, Dermoscopy and Other Selected Noninvasive Dermatologic Tests, Number: 0188, Last review date: 02/13/2025. [Cited 07/14/2025]

Publication History

09-25-19	Effective for DecisonDX-Melanoma testing for cutaneous melanoma coverage only for Medicare but not for Centennial Care and Commercial.
11-18-20	Annual review. No change. Reviewed 11-02-20. Continue to follow LCD L38018 and will remain as a covered benefit for Medicare members only. Will remain as a non-covered benefit for Centennial and Commercial. CPT code 81599 will remain on the PA grid.

07-28-21 Annual review. Reviewed by the PHP Medical Policy Committee on 06/11/22021. Reviewed by TAC 07/15/2021 to evaluate coverage for non-Medicare. The criteria will continue to follow L38018 DecisionDx-Melanoma for Medicare only. Based on no validation of GEP tests platforms by NCCN and Hayes DecisionDx Melanoma test will be non-covered for Centennial and Commercial. Add new 2021 code 81529 to PA grid for all LOB. Verified with Castle Bioscience at 800-788-9007 the new code 81529 is for DecisionDX Melanoma testing and no need for 81599, but LCA A56636 still has 81599 listed.

07-26-2022 Annual review. Reviewed by PHP Medical Policy Committee on 06-01-2022. Continue DecisionDx Melanoma test for Medicare only and to continue to follow LCD L38018. LCD revised verbiage under 2a and 2b under covered indications. DecisionDx Melanoma test will continue non-coverage for non-Medicare based on Hayes and NCCN. Add code 81599 and 81479. Continue PA requirement for 81529, 81479 and 81599.

07-26-2023 Annual review. Reviewed by PHP Medical Policy Committee on 06/28/2023. **DecisionDX Melanoma** considered experimental. Rationale: Both the Novitas LCD and NCCN, say there is insufficient evidence to support incorporation of current GEP tests into melanoma care. Novitas, LCD L39365/A59125 clearly outlines DecisionDX-Melanoma code (81529) is not medically reasonable and necessary because the literatures concerning DecisionDx-Melanoma is insufficient to establish the analytic validity, clinical validity, and clinical utility of this test in the Medicare population. Code 81529 will be configured as investigational for ALOB.
New test, **myPath Melanoma** (code 0090U) added for ALOB. MyPath is a test for suspicious skin lesion. MyPath will follow Novitas, Genetic Testing for Oncology, LCD (L39365) and LCA (A59125) – covers for diagnostic test for neoplasm uncertain behavior of the lip or skin for ALOB. Code 0090U will be config to require PA for ALOB.

08-21-2024 Annual review. Reviewed by PHP Medical Policy Committee on 07/17/2024 and 07/19/2024.
MyPath Melanoma (0090U), change are as follow:
Changed coverage to only allow for Medicare which will continue to follow Novitas, Genetic Testing for Oncology, LCD (L39365) and related article LCA (A59125).
Changed coverage for Medicaid and Commercial to non-covered. NCCN, UpToDate, MCG consider gene expression profiling (GEP) investigational, or unproven and therefore not covered. Configure myPath Melanoma CPT code (0090U) as investigational and experimental for Medicaid and Commercial and continue PA requirement for ALOB.

DecisionDx-Melanoma (81529), no change:
Continue as non-covered for Medicare, Medicaid, and Commercial. PHP will continue to follow NCCN and Novitas, Genetic Testing for Oncology, LCD (L39365). CMS, NCCN, UpToDate, MCG consider gene expression profiling (GEP) investigational, or unproven and therefore not covered. Update previous request to config code 81529 for ALOB submitted in 2023. Re-request to configure CPT code (81529) as investigational for Medicare. Will use the same effective date as the initial request used to config commercial and Medicaid, back in 2023. Note: the provider communication was completed 2023 regarding config of code 81529.

DecisionDx® DiffDx™- Melanoma (0314U), new test added:
Coverage is for Medicare only and will follow Novitas, Genetic Testing for Oncology, LCD (L39365) and related article LCA (A59125).
Non-covered for Medicaid and Commercial. NCCN, UpToDate, MCG consider gene expression profiling (GEP) investigational, or unproven and therefore not covered. Configured DecisionDx DiffDx Melanoma CPT code (0314U) as experimental for Medicaid and Commercial and continue PA requirement for ALOB.

Pigmented Lesion Assay (PLA) by DermTech (0089U), new test added for information only. See Investigative & New Technology Assessment List (Non-Covered Services), MPM 36.0.

3-26-2025 Ad Hoc Review: Reviewed policy to match LOD #42. 0090U and 0314U have been moved to follow Medicare for Medicaid services, following WPS LCD/LCA. 81529 remains non-covered as NCCN guidelines show this is investigational and experimental.

5-28-2025 Ad Hoc Review: Reviewed MPM 36.0 I & E, which covers annual review of PLA, 0089U. In review, LCD/LCA coverage from Wisconsin applies for local guidance, allowing PLA for both Medicare and Medicaid. This has been removed from our investigational policy and added to this MPM. PLA, 0089U still remains investigational for commercial plans following NCCN and/or

	MCG guidance as “uncertain”. Correction to the incorrect ad-hoc date: changed from 03/13/25 to 03/26/2025.
08-27-2025	Annual review. Reviewed by PHP Medical Policy Committee on 07/09/2025. Continue coverage for Medicare and Medicaid only for 1). myPath Melanoma (0090U); 2). DecisionDx® DiffDx™ Melanoma (0314U) and 3). Pigmented Lesion Assay (PLA) by DermTech (0089U). 4). DecisionDx Melanoma (81529) which was moved from exclusion section to covered status. Configuration of I&E will be removed for code 81529 for Medicare and Medicaid. Prior authorization will be required for all (4) GEP tests for Medicare & Medicaid. Coverage for ALL (4) tests mentioned above are non-covered for Commercial based on position statement provided by the leading oncology source NCCN. Configuration of these codes as investigational and experimental will continue for commercial line of business.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.
For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: ***Click here for Medical Policies***

Web links:
At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.