

Subject: Genetic Testing for Cutaneous Melanoma

Medical Policy #: 7.7

Status: Reviewed

Original Effective Date: 09/25/2019

Last Annual Review Date: 08/21/2024

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.

Determination

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

1. **myPath Melanoma:**

Prior authorization is required for (00904).

Medicare:

PHP follows Novitas, Genetic Testing for Oncology, LCD ([L39365](#)) and related article LCA ([A59125](#)). This test is for diagnostic test for neoplasm of uncertain behavior of the lip or skin. Medicaid and Commercial.

Non-covered for Medicaid and 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-Melanoma (81529):**

Non-covered for Medicare, Medicaid, and Commercial.

PHP follows National Comprehensive Cancer Network (NCCN) and Novitas, Genetic Testing for Oncology, LCD [L39365](#), that testing with GEP is considered experimental, investigational, or unproven and therefore not covered.

3. **DecisionDx@ DiffDx™- Melanoma:**

Prior authorization is required for (0314U).

Medicare:

PHP follows Novitas, Genetic Testing for Oncology, LCD ([L39365](#)) and related article LCA ([A59125](#)). This test is for diagnostic test for neoplasm of uncertain behavior of the lip or skin.

Non-covered for Medicaid and 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.

4. **Pigmented Lesion Assay (PLA) by DermTech (0089U).** See Investigative & New Technology Assessment List (Non-Covered Services), MPM 36.0.

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.
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)
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)

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee (PHCQC): Clinton White MD

Senior Medical Director: Jim Romero MD

Date Approved: 08/21/2024

References

1. CMS, Novitas, Genetic Testing for Oncology, LCD L39365, effective date 07/17/2023. [Cited 06/27/2024]
2. CMS, Novitas, Billing and Coding: Genetic Testing for Oncology, LCA (A59125), Effective date:07/17/2023. [Cited 06/27/2024]
3. CMS, Local Coverage Determination, MoIDX: DecisionDX-Melanoma (L38018), Wisconsin, J-05, Effective Date 08/12/2019, Revision date: 06/20/2024, R#5. [Cited 06/27/2024]
4. CMS, Local Coverage Article, Billing and Coding for MoIDX: DecisionDX-Melanoma (A56636), Effective date 08/12/2019, Revised Date: 07/03/2022, R#7. [Cited 06-27-2024]
5. CMS, Local Coverage Determination, MoIDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma (L39479), Updated on 06/22/2023 [Cited 07/02/2024]
6. CMS, Local Coverage Determination, MoIDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma, (A59261), revision date 08/13/2023 R1 [Cited 07/02/2024]
7. National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2024 — April 03, 2024, Cutaneous Melanoma, [Cited 06-28-2024]Hayes, DecisionDX-Melanoma, Molecular Test Assessment Mar 29, 2022, Annual Review: Feb 27, 2024, SOMATIC. [Cited 07/11/2024]
8. MCG, Melanoma (Cutaneous) - Gene Expression Profiling, A-0837, Ambulatory Care 28th Edition, Last Update: 3/14/2024 [Cited 07/11/2024]
9. Hayes, myPath Melanoma (Castle Biosciences Inc.), Precision Medicine Research Brief, Jun 27, 2023 | SOMATIC. [Cited 06/28/2024]
10. UpToDate, Tumor, node, metastasis (TNM) staging system and other prognostic factors in cutaneous melanoma, Literature review current through: Jun 2024. This topic last updated: Jan 03, 2023. , [Cited 07/11/2024]
11. Aetna, Tumor Markers, #0352, Last review: 06/26/2024, Next review:04/10/2025. [Cited 07/11/2024]Cigna, Molecular and Proteomic Diagnostic Testing for Hematology and Oncology Indications, No. 0520, Effective date: 04/15/2024, Next review: 05/15/2025. [Cited 07/11/2024]
12. Humana, Gene Expression Profiling, No. HUM-0458-059, Effective Date: 01/01/2024, Revision Date: 01/01/2024, Review Date: 04/27/2023. [Cited 07/11/2024]
13. UnitedHealthcare, Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions, [Cited 07/11/2024]

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.

Not every Presbyterian health plan contains the same benefits. Please refer to the member's specific benefit plan and Schedule of Benefits to determine coverage [MPMPPC051001].

- 07-28-21 Annual review. Reviewed by the PHP Medical Policy Committee on 06/11/2021. 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.

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.