Subject: Genetic Testing for Uveal Melanoma

Medical Policy #: 7.9

Original Effective Date: 11/20/2019

Status: Reviewed

Last Review Date: 03-26-2025

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

Uveal melanoma is a rare cancer, and most common intra-ocular cancer in adults.

DecisionDx-UM is an RNA gene expression classifier that is based on the expression levels of 15 mRNA transcripts (3 control and 12 discriminating genes).

DecisionDx-UM is performed on tissue from a fresh-frozen fine needle aspirate biopsy (FNAB), formalin-fixed paraffin embedded (FFPE) sections from an enucleated tumor, or, in rare cases, fresh-frozen resection material. DecisionDX-UM results are reported as a 5-year risk classification for metastasis: low-risk (Class 1A), intermediate risk (Class 1B), or high risk (Class 2).

The DecisionDx-UM test is intended for determination of metastatic risk, and to guide surveillance and referral to medical oncology in patients who have a confirmed diagnosis of UM and no evidence of metastatic disease. The test discriminates patients with high risk (class 2) for early distal recurrent disease from those with minimal risk of distal metastasis (class 1A). Identification of high-risk patients allows early referral to a medical oncologist with expertise in the management of UMs, which includes intensified metastatic surveillance and/or metastasis intervention, and stratification for entry into clinical trials with adjuvant therapy. In rare cases where the patient cannot realistically see a medical oncologist due to geographic location (long distance to travel), and/or are among underserved patient populations, if they cannot feasibly see a medical oncologist, surveillance testing for class 2 patients can be directed by an ophthalmologist with specific training in treating patients with UM.

Coverage Determination

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

Decision Dx-UM (Uveal Melanoma) test is covered for Medicare, Medicaid and Commercial members.

Presbyterian Health Plan considers DecisionDX-UM (uveal melanoma) medically necessary and uses two-mandated coverage statements to address this benefit. PHP follows WPS, CMS MoIDX: Decision Dx-UM (Uveal Melanoma) (L37210) and Novitas LCD Biomarkers for Oncology (L35396) for Prognostic of Uveal Melanoma (GNAQ and GNA11).

Intended Use:
DecisionDX-UM assay is intended for determination of metastatic risk, and to guide surveillance and referral to medical oncology.
Decision DX-UM may be covered for **ALL** of the following:
- have a confirmed diagnosis of uveal melanoma (UM) and
- no evidence of metastatic disease.

Coding

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

CPT Codes	Description
81552	Oncology, (uveal melanoma) mRNA, gene expression profiling by real-time RT-PCR of 15 genes (**CDH1, ECM1, EIF1B, FXR1, HTR2B, ID2, LMCD1, LTA4H, MTUS1, RAB31, ROBO1, SATB1**; and three control genes, **MRPS21, RBM23**, and **SAP130**. The three utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis. Recommended by LCD L37210 and A57566, MoIDX: Decision Dx-UM.

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].

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CPT Codes	Description
81479	Decision DX-Uveal Melanoma (GNA11), unlisted molecular pathology. Recommended by LCD L35396- and A52986 Biomarkers for Oncology. **Note**: A description of the testing performed is required in the narrative/remarks when using this code.
81403	Molecular pathology procedure, Level 4 (e.g, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons). Recommended by LCD L35396- and A52986 Biomarkers for Oncology. *GNAQ (guanine nucleotide-binding protein G[q] subunit alpha)* (eg, uveal melanoma), common variants (eg, R183, Q209).

ICD-10 CODE	For most current diagnosis for Uveal Melanoma see below
For CPT **81552**, covered ICD-10 codes per LCD (**L37210**), see related policy article (A57566) For CPT **81479** and **81403**, covered ICD-10 codes per LCD (L35396), see related policy article (A52986)	

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee: Clinton White MD
Senior Medical Director: Jim Romero MD
Date Approved: 03/26/2025

References

1. CMS, WPS, Local Coverage Determination, MolDX: Decision Dx-UM (Uveal Melanoma) (L37210), WPS, Revision date 06-30-2022, R7, with related Article A57566, effective date 01/01/2020 revision date: 06-30-22 R2. [Cited 01/13/2025]
2. CMS, Novitas Solutions, Local Coverage Determination Biomarkers for Oncology (L35396), revised 12/13/20, R32, with related Article, Billing and Coding for Biomarkers for Oncology (A52986), revision date 10/01/2023, R42. [Cited 01/13/2025]
3. NCCN Guidelines Version 1.2024 – May 23, 2024, Treatment by Cancer type, Melanoma: Uveal, [Cited 01/13/2025]
4. Hayes, DecisionDX-UM (Castle Biosciences Inc.), Jun 17, 2020. Annual review May 08,2023 [Cited 01/13/2025]
5. MCG Health Ambulatory Care 28th Edition, Melanoma (Uveal)-Gene Expression Profiling, ACG: A-0670 (AC), Last update: 09/2023. [Cited 01/13/2025]
6. Hayes, DecisionDx-Melanoma, Molecular Test Assessment, Aug 31, 2018, Annual Review Mar 31, 2023. [Cited 01/13/2025]

Publication History

11/20/2019:   Presented to Technology Assessment Committee on 10/16/2019. Resulted in creation of MPM 7.9 for DecisonDX-UM (Uveal Melanoma) testing coverage for Medicare, Medicaid (Centennial) and Commercial.

01/27/2021:   Annual review. Reviewed by PHP Medical Policy Committee on 01/06/2021. No change to criteria, will continue to follow LCD L37210 and L35396 for all LOB. Code update: Added 81552 & removed deleted code 0081U. CPT code 81552 will now require PA for all LOB; and 81479 and 81403 will remain on PA grid.

01/26/2022:   Annual review. Reviewed by PHP Medical Policy Committee on 12/10/2021. No change. Continue to follow LCD (L37210) and LCD (L35396). Continue PA for 81552, 81479 and 81403. Genes (GNA11 AND GNAQ) is mentioned by NCCN but not the 15 genes: CDH1, ECM1, EIF1B, FXR1, HTR2B, ID2, LMCD1, LTA4H, MTUS1, RAB31, ROBO1, SATB1; and three control genes, MRPS21, RBM23, and SAP130 (code 81552), might be why there is no utilization.

01-25-23   Annual review. Reviewed by PHP Medical Policy Committee on 11/16/2022. No change. Continue to follow LCD (L37210) and LCD (L35396). Continue PA for 81552, 81479 and 81403. Not recommended as Social Determination of Health (SDOH). Updated the Description section with language from LCD L35396 for circumstances surrounding SDOH.

02-07-24   Annual review. Reviewed by PHP Medical Policy Committee on 12/08/2023. No change. Continue to follow WPS LCD (L37210) and Novitas LCD (L35396) for ALOB. Continue PA for 81552, 81479 and 81403.

03-26-25   Annual review. Reviewed by PHP Medical Policy Committee on 01-15-2025. Continue to follow WPS LCD (L37210) and Novitas LCD (L35396) for ALOB. Continue PA for the molecular codes 81479 and 81403. Remove PA requirement for 81552 for ALOB, since there has not been any utilization since 2023.

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].

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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.