Medicare Medical Policy

Gene Expression Profile Testing for Melanoma

MEDICARE MEDICAL POLICY NUMBER: 253

Effective Date: 10/1/2024

Last Review Date: 9/2024

Next Annual Review: 9/2025

MEDICARE COVERAGE CRITERIA 2
POLICY CROSS REFERENCES 3
POLICY GUIDELINES 3
REGULATORY STATUS 3
BILLING GUIDELINES AND CODING 4
REFERENCES 5
POLICY REVISION HISTORY 5

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Decision DX-UM (Uveal Melanoma) (81552; Castle Bioscience, Inc., Phoenix, AZ)	Local Coverage Determination (LCD): Decision DX-UM (Uveal Melanoma) (L37072)
Decision DX-Melanoma (81529; Castle Bioscience, Inc., Phoenix, AZ)	LCD: MolDX: Melanoma Risk Stratification Molecular Testing (L37748) **NOTE:** This LCD requires successful completion of a technical assessment (TA) for each test; the DecisionDX-Melanoma test **meets** this LCD requirement.
MyPath Melanoma Assay (0090U; Castle Biosciences, Inc., Phoenix, AZ or Myriad Genetics, UT) *DecisionDx® DiffDx™-Melanoma (0314U; Castle Biosciences, Inc.)*	LCD: MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma (L39375) *(**NOTE:** The LCD requires successful completion of TA review of each test.)* • Both the DecisionDx® DiffDx™-Melanoma and MyPath™ Melanoma tests **do** meet this LCD requirement and therefore may be considered **medically necessary** when all other LCD criteria are met.
Pigmented Lesion Assay (PLA; 0089U; DermTech, Inc., La Jolla, CA)	LCD: MolDX: Pigmented Lesion Assay (L38151)

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

Medicare's Molecular Diagnostic (MolDX) Program Contractor

Laboratories performing tests in service areas which have adopted guidelines or coverage determinations made by the Medicare Molecular Diagnostics (MolDX) Program contractor are required to submit a technology assessment (TA) to establish analytical and clinical validity (AV/CV) and clinical utility (CU). Supporting LCDs regarding TA reviews include, but are not limited to, the following:

- Laboratories in CA & NV: LCD for MolDX: Molecular Diagnostic Tests (MDT) (L35160)
- Laboratories in NC, SC, GA, TN, AL, VA, & WV: LCD for MolDX: Molecular Diagnostic Tests (MDT) (L35025)
- Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, & WY: LCD for MolDX: Molecular Diagnostic Tests (MDT) (L36256)

Coverage or non-coverage determinations made by MolDX are maintained in the DEX™ Diagnostics Exchange registry catalog and are available for public viewing. If a test does not have a coverage determination by the MolDX Program, then AV/CV and CU have **not** been established and the test is considered not medically reasonable and necessary under *SSA §1862(a)(1)(A)* until a MolDX review is complete and coverage is indicated by MolDX or Noridian. Therefore, tests identified in this policy as not meeting this requirement are not medically reasonable or necessary for Medicare under *SSA §1862(a)(1)(A).*

Prior to August 6, 2023, the DecisionDX DiffDx-Melanoma test had been reviewed by the MolDX Program Contractor and was listed within the DEX™ Diagnostics Exchange Registry as a "Not Covered" test. Therefore, the DecisionDx DiffDx-Melanoma test was previously considered not medically necessary. According to communication from the MolDX Program Contractor, this test became eligible for coverage when all applicable LCD criteria are met as of August 6, 2023.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the

availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

Please see the following LCAs for applicable billing guidelines:

- Billing and Coding: MolDX: DecisionDx-UM (Uveal Melanoma) (A57622)
- Billing and Coding for MolDX: DecisionDX-Melanoma (A56636)
- Billing and Coding: MolDX: Melanoma Risk Stratification Molecular Testing (A57290)
- Billing and Coding: MolDX: myPath Melanoma Assay (A57627)
- Billing and Coding: MolDX: Pigmented Lesion Assay (A58052)
- Billing and Coding: MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma (A59181)

CODES*		
CPT	0089U	Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es) *(Used to report Pigmented Lesion Assay (PLA) by DermTech)*
	0090U	Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant) *(Used to report myPath® Melanoma by Castle Biosciences)*
	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) *(Used to report DecisionDx® DiffDX™- Melanoma by Castle Biosciences)*
	81401	Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)
	81479	Unlisted molecular pathology procedure
	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 *(Used to report DecisionDx-Melanoma by Castle Biosciences)*
	81552	Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis *(Used to report DecisionDx-UM by Castle Biosciences)*
	81599	Unlisted multianalyte assay with algorithmic analysis
	84999	Unlisted chemistry procedure
HCPCS	None	

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
10/2022	Annual review (converted to new format 2/2023)
8/2023	Interim update; update CMS LCD/LCA references for assays used for cutaneous melanoma
10/2023	Annual review; no changes to criteria, update title
12/2023	Update MolDX coverage information for the DecisionDx DiffDx-Melanoma test
10/2024	Annual review; no changes to criteria