MEDICAL POLICY	Genetic Testing: Gene Expression Profile Testing for Melanoma (Medicare Only)
Effective Date: 10/1/2022  10/1/2022 Medical Officer Date	Medical Policy Number: 253 Medical Policy Committee Approved Date: 7/19; 11/19; 7/2020; 9/2020; 12/2020; 9/2021; 11/2021; 3/2022; 9/2022

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare Only

MEDICAL POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

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 (81599; 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.)	LCD: MolDX: myPath Melanoma Assay (L37881)
Pigmented Lesion Assay (PLA; 0089U; DermTech, Inc., La Jolla, CA)	LCD: MolDX: Pigmented Lesion Assay (L38151)

DecisionDx® DiffDx™-Melanoma (0314U; Castle Biosciences, Inc.)	This test is considered **not medically necessary**, based on Medicare guidelines. *See "Policy Guidelines" below.*

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).*

The DecisionDX DiffDx-Melanoma test has been reviewed by the MolDX Program Contractor and is listed within the DEX™ Diagnostics Exchange Registry as a "Not Covered" test.

BILLING GUIDELINES

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)

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
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)*
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)
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)*
Not Covered	
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)*
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then **prior-authorization is required.**	
81479	Unlisted molecular pathology procedure
81599	Unlisted multianalyte assay with algorithmic analysis
84999	Unlisted chemistry procedure

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

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.