


MEDICAL POLICY		Genetic Testing: Gene Expression Profile Testing for Melanoma (Medicare Only)	
Effective Date: 1/1/2021		Section: GT	Policy No: 443
 <div style="text-align: right;">1/1/2021</div>		Medical Policy Committee Approved Date: 7/19; 11/19; 7/2020; 9/2020; 12/2020	
		Medical Officer	Date

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	
<p>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.</p> <p>This Medicare guidance was identified as of the last policy review date on 7/29/2020.</p>	
Service	Medicare Guidelines
<i>Decision DX-UM (Uveal Melanoma)</i>	<ul style="list-style-type: none"> Local Coverage Determination: Decision DX-UM (Uveal Melanoma) (L37072)¹ Local Coverage Article: Billing and Coding: MoIDX: DecisionDx-UM (Uveal MELANOMA) (A57622)²
<i>Decision DX-Melanoma</i>	<ul style="list-style-type: none"> Local Coverage Determination: Decision DX-Melanoma (L37748)³ Local Coverage Article: Billing and Coding: MoIDX: DecisionDx-Melanoma (A57418)⁴ Local Coverage Article: Billing and Coding: MoIDX: Melanoma Risk Stratification Molecular Testing (A57290)⁵
<i>MyPath Melanoma Assay</i>	<ul style="list-style-type: none"> Local Coverage Determination (LCD): MoIDX: myPath Melanoma Assay (L37881)⁶ Local Coverage Article: Billing and Coding: MoIDX: myPath MELANOMA Assay (A57627)⁷

MEDICAL POLICY	Genetic Testing: Gene Expression Profile Testing for Melanoma (Medicare Only)
-----------------------	--

<i>Pigmented Lesion Assay</i>	<ul style="list-style-type: none"> Local Coverage Determination (LCD): MoIDX: Pigmented Lesion Assay (L38153)⁸ Local Coverage Article: Billing and Coding: MoIDX: Pigmented Lesion Assay (A58053)⁹
-------------------------------	--

BILLING GUIDELINES

Please see the following Local Coverage Articles for applicable billing guidelines:

- Local Coverage Article: Billing and Coding: MoIDX: DecisionDx-UM (Uveal MELANOMA) ([A57622](#))²
- Local Coverage Article: Billing and Coding for MoIDX: DecisionDX-MELANOMA ([A56636](#))^{4,10}
- Local Coverage Article: Billing and Coding: MoIDX: myPath MELANOMA Assay ([A57627](#))⁷
- Local Coverage Article: Billing and Coding: MoIDX: Pigmented Lesion Assay ([A58053](#))⁹

CPT CODES

Medicare Only	
Prior Authorization Required	
0081U	TERMED 12/31/19 Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping genes), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis
0089U	Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es)
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, indeterminate, malignant)
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)
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
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

MEDICAL POLICY	Genetic Testing: Gene Expression Profile Testing for Melanoma (Medicare Only)
-----------------------	--

<p>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.</p>	
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.

REFERENCES

- Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD): MoIDX: DecisionDx-UM (Uveal Melanoma) (L37072). Effective: 02/21/2019.
<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37072>. Accessed 7/28/2020.
- Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: MoIDX: Decision Dx-UM (Uveal MELANOMA) (A57566). Effective Date, 1/01/2020.
<https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57566>. Accessed 7/29/2020.

MEDICAL POLICY	Genetic Testing: Gene Expression Profile Testing for Melanoma (Medicare Only)
-----------------------	--

3. Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD): MoIDX: DecisionDx-Melanoma (L37748). Effective: 02/10/2019. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37748>. Accessed 7/28/2020.
4. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: MoIDX: DecisionDx-MELANOMA (A57418). Effective Date, 11/01/2019. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57418>. Accessed 7/29/2020.
5. Centers for Medicare & Medicaid Services (CMS) Local Coverage Article: Billing and Coding: MoIDX: Melanoma Risk Stratification Molecular Testing (A57290). <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57290&ver=7&keyword=A57290>. Published 2020. Accessed 12/11/2020.
6. Centers for Medicare & Medicaid Services Local Coverage Determination: MYPATH Melanoma Assay (L37881). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37881>. Published 2019. Accessed 7/28/2020.
7. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: MoIDX: myPath Melanoma Assay (A57627). Revision effective date, 11/01/2019. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57627>. Accessed 7/29/2020.
8. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): MoIDX: Pigmented Lesion Assay (L38153). Effective date, 6/07/2020. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=38153>. Accessed 7/29/2020.
9. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: MoIDX: Pigmented Lesion Assay (A58053). Effective date, 6/07/2020. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=58053>. Accessed 7/29/2020.
10. Centers for Medicare & Medicaid Services Local Coverage Article: Billing and Coding for MoIDX: DecisionDX-MELANOMA (A56636) <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56636>. Published 2019. Accessed 7/28/2020.