GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Cutaneous melanoma represents less than 5% of skin malignancies but results in the most skin cancer deaths. The incidence of cutaneous melanoma continues to increase, and it is currently the sixth most common cancer in the United States. Standard treatment options for stage 1 and 2 melanoma are excision with or without sentinel lymph node examination. Current risk factors to predict localized tumor aggression include Breslow tumor thickness, tumor ulceration, and mitotic rate of the tumor cells. Regional lymph node involvement significantly negatively impacts the rate of survival, and the likelihood of which increases with increasing tumor thickness.

The DecisionDx-Melanoma test is a multigene expression assay designed to predict metastasis in individuals with stage I or stage II cutaneous melanoma who have no sign of disease beyond the original tumor. The laboratory test is a signature of 31 genes, 28 discriminating genes and 3 control genes, that classifies tumors as class 1 (low risk of metastasis) or class 2 (high risk of metastasis), using reverse transcription polymerase chain reaction (RT-PCR) on formalin-fixed paraffin-embedded (FFPE) primary tumor tissue specimens obtained from either biopsy or excision of the cutaneous melanoma.

myPath Melanoma is a clinically validated test to be used as an adjunct to histopathology when the distinction between a benign nevus and a malignant melanoma cannot be made confidently by histopathology alone. The test measures the expression of 23 genes by qRT-PCR methodology and distinguishes melanoma from nevi with a sensitivity of 90% and a specificity of 91%. An algorithm is applied that combines the measurements of gene expression, assigns a weight to each gene component, and establishes a threshold value. The result is a single numerical score that classifies a melanocytic lesion as ‘likely benign,’ ‘likely malignant,’ or ‘indeterminate.’

Uveal melanoma (UM), also called ocular melanoma, is the most common form of primary eye cancer. UM affects the iris, ciliary body, and choroid portions of the uveal tract. UM is an aggressive cancer that often forms undetectable micrometastases before diagnosis of the primary tumor. The main goals of treatment are to reduce the risk of metastasis, prevent local growth and destruction of ocular tissues and preserve as much vision as possible.

DecisionDx-UM determines the molecular signature of a patient's tumor. The DecisionDx-UM test is also known as the gene expression profile test for uveal melanoma. The results of the test provide knowledge regarding the risk of near term metastasis (5 years). Tumors with a Class 1 signature are associated with a good prognosis and a low potential to metastasize, while tumors with a Class 2 signature have a high potential to spread. The DecisionDX tests are available only from Castle Biosciences Inc.

POLICY
myPath Melanoma test does not prior require authorization for all product lines.

DecisionDX-Melanoma test is non-covered for all product lines.

DecisionDX-UM is non-covered for HMO, PPO, Individual Marketplace, & Advantage.

DecisionDX-UM does not require prior authorization for Elite.

Paramount considers gene expression profiling of cutaneous melanoma with myPath Melanoma medically necessary when it is used by a dermatopathologist as an adjunct to histopathology because the distinction between a benign nevus and a malignant melanoma cannot be made confidently by histopathology alone.

Paramount considers gene expression profiling of cutaneous melanoma with DecisionDX-Melanoma experimental and investigational because of insufficient data on their analytical validity, clinical validity, and clinical utility.
HMO, PPO, Individual Marketplace, Elite, Advantage

Paramount considers gene expression profiling of uveal melanoma (DecisionDX-UM) experimental and investigational because of insufficient data on their analytical validity, clinical validity, and clinical utility.

Elite

Gene expression profiling of uveal melanoma (DecisionDX-UM) may be medically necessary for risk stratification of persons with localized uveal melanoma.

Elite members have limited coverage for the DecisionDx-UM (Castle Bioscience, Inc.) test for the management of newly diagnosed uveal melanoma. This test is intended for the determination of metastatic risk, and to guide surveillance and referral to medical oncology (preferably an oncologist with expertise in melanoma) in patients who have a confirmed diagnosis of uveal melanoma (UM) and no evidence of metastatic disease.

CODING/BILLING INFORMATION

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

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<thead>
<tr>
<th>CPT CODES</th>
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<tr>
<td>81599</td>
<td>Unlisted multianalyte assay with algorithmic analysis</td>
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<table>
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<tr>
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<td>C69.32</td>
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<td>C69.41</td>
<td>Malignant neoplasm of right ciliary body</td>
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<td>C69.42</td>
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<td>C69.91</td>
<td>Malignant neoplasm of unspecified site of right eye</td>
</tr>
<tr>
<td>C69.92</td>
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TAWG REVIEW DATES: 11/14/2012, 03/21/2014, 03/19/2015, 03/25/2016, 05/27/2016, 08/25/2017, 07/26/2018

REVISION HISTORY EXPLANATION

03/21/14: Policy reviewed and updated to reflect most current clinical evidence. Policy approved per The Technology Assessment Working Group (TAWG) committee as revised.

03/19/15: Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

03/25/16: Added code 81599 to policy. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

05/27/16: Changed title from DecisionDX-UM to Gene Expression Profiling of Melanomas. Added DecisionDx-Melanoma for Cutaneous Melanoma as non-covered to policy. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

08/25/17: Added myPath Melanoma for cutaneous melanoma as covered without prior authorization for all product lines. DecisionDX-UM is now covered without prior authorization for Elite only per CMS guidelines. Removed code 84999 and added ICD-10 codes C69.31, C69.32, C69.41, C69.42, C69.91, C69.92 to policy per CMS guidelines. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

07/26/18: Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://jfs.ohio.gov/
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.