Current Effective Date: 12/19/24
Status: Approved
Reviewed by Medical Policy Subcommittee: 5/9/19, 2/3/22, 12/19/24
Reviewed Dates: 8/25/17, 3/28/19, 2/3/22, 12/3/24

INSTRUCTIONS FOR USE DISCLAIMER:
SummaCare posts policies relating to coverage and medical necessity issues to assist members and providers in administering member benefits. These policies do not constitute a contract or agreement between SummaCare and any member or provider. The policies are guidelines only and are intended to assist members and providers with coverage issues. SummaCare is not a health care provider, does not provide or assist with health care services or treatment, and does not make guarantees as to the effectiveness of treatment administered by providers. The treatment of members is the sole responsibility of the treating provider, who is not an employee of SummaCare, but is an independent contractor in private practice. The policies posted to this site may be updated and are subject to change without prior notice to members or providers.

Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Melanoma Policy

Indication/Usage:

Myriad Genetic Laboratories has developed myPath® Melanoma, 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 9094% and a specificity of 91-96%. (Myriad myPath, 2017)

DecisionDx-Melanoma is a multigene expression test that analyzes 28 genes demonstrated to have differential expression between metastatic and nonmetastatic melanoma tumors. It is performed on formalin-fixed paraffin-embedded (FFPE) tumor tissue specimens of a patient's primary CM tumor. The test uses a radial basis machine algorithm to classify patients into a with increasing probability of recurrence and/or metastasis within 5 years of diagnosis: low (Class 1A), intermediate (Class 1B or 2A), or high (Class 2B) risk.[HD2] (Castle Biosciences, 2021)

Skin cancer is a common cancer, with melanoma being the most fatal type. Survival is greatly increased if diagnosed when localized (Voss et al., 2015). In some cases, histopathology may not be able to differentiate between benign and malignant lesions. Therefore, additional evaluations are needed (Rogers T, 2016). MyPath Melanoma is a gene expression signature that is intended to help differentiate between malignant melanoma and benign nevi. (Hayes, 2017)

Medical Indications for Authorization Commercial Members

SummaCare considers Decision Dx-UM (Uveal Melanoma) medically necessary 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.

SummaCare considers the MyPath Melanoma assay medical necessary for the diagnosis or exclusion of melanoma from a biopsy when all of the following clinical conditions are met:

- The test is ordered by a board certified dermapathologist
- The specimen is a primary cutaneous melanocytic neoplasm for which the diagnosis is equivocal \ uncertain eq (i.e., clear distinction between benign or malignant cannot be achieved using clinical and/or histopathological features alone)
- The patient may be subject to additional intervention such as re-excision and/or sentinel node biopsy as a result of the diagnostic uncertainty.

Medicare Members CMS CGS LCD ID L37130 MolDX: DecisionDx-UM (Uveal Melanoma) Coverage Guidance Coverage Indications, Limitations, and/or Medical Necessity

This Medicare contractor will provide 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.

CGS LCD ID L39389 MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma Coverage Guidance Coverage Indications, Limitations, and/or Medical Necessity

The purpose of this test is to assist dermatopathologists to arrive at the correct diagnosis of melanoma versus non-melanoma when examining skin biopsies.

This Medicare contractor will provide limited coverage for molecular Deoxyribonucleic acid (DNA)/Ribonucleic acid (RNA) assays that aid in the diagnosis or exclusion of melanoma from a biopsy when ALL of the following clinical conditions are met:

- The test is ordered by a board-certified or board-eligible dermatopathologist
- The specimen is a primary (non-metastatic, non-re-excision specimen) cutaneous melanocytic neoplasm for which the diagnosis is equivocal/uncertain (i.e., clear distinction between benign or malignant cannot be achieved using clinical and/or histopathological features alone) despite the performance of standard-of-care test procedures and relevant ancillary tests (i.e., immunohistochemical stains)
- The specimen includes an area representative of the lesion or portion of the lesion that is suspicious for malignancy
- The patient may be subjected to additional intervention, such as re-excision and/or sentinel lymph node biopsy, as a result of the diagnostic uncertainty
- The patient has not been tested with the same or similar assay for the same clinical indication
- The test is validated for use in the intended-use population and is performed according to its stated intended-use
- The test demonstrates Analytical and Clinical Validity (AV and CV) and Clinical Utility (CU) and undergoes a technical assessment (TA) by MolDx®to demonstrate compliance of the service with this policy

Tests that demonstrate similar indicated uses and equivalent or superior performance to covered tests may similarly be covered under this policy.

Limitations

There is limited evidence supporting the myPath Melanoma test as a diagnostic adjunctive tool to distinguish benign nevi from melanoma when there is ambiguity of the histopathology report. There is insufficient evidence to support the clinical use of myPath Melanoma as a guide to manage treatment decisions. Studies are limited in establishing that the test results have a positive impact on health outcomes. (Hayes, 2018)

There is insufficient evidence to support the use of the DecisionDx-UM test to identify the likelihood of metastasis within 5 years in patients with UM. Although an established assay process is in place, the validity of the test and the impact on patient management is unclear; additional data are needed to support the use of this test. (Hayes, 2021)

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research.

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

Hayes GTE (Genetic Test Evaluation Overview) found that there is limited evidence supporting the myPath Melanoma test as a diagnostic adjunctive tool to distinguish benign nevi from melanoma when there is ambiguity of the histopathology report. Studies are limited in establishing that the test results have a positive impact on health outcomes (Hayes, Inc, 2018)

American Cancer Society. Key Statistics for Melanoma Skin Cancer. https://www.cancer.org/cancer/types/melanoma-skin-cancer/about/key-statistics.htm

Wendt J, Rauscher S, Burgstaller-Muehlbacher S, et al. Human determinants and the role of melanocortin-1 receptor variants in melanoma risk independent of UV radiation exposure. JAMA Dermatol. Jul 1 2016;152(7):776-782. PMID 27050141.

Wiesner T, Obenauf AC, Murali R, et al. Germline mutations in BAP1 predispose to melanocytic tumors. Nat Genet. Aug 28 2011; 43(10):1018-1021. PMID 21874003.

Chen T, Fallah M, Forsti A, et al. Risk of next melanoma in patients with familial and sporadic melanoma by number of previous melanomas. JAMA Dermatol. Jun 2015; 151(6):607-615. PMID

Jiang AJ, Rambhatla PV, Eide MJ. Socioeconomic and lifestyle factors and melanoma: a systematic review. Br J Dermatol. Apr 2015; 172(4):885-915. PMID 25354495.

Wilson RL, Yentzer BA, Isom SP, et al. How good are US dermatologists at discriminating skin cancers? A number-needed-to-treat analysis. J Dermatolog Treat. Feb 2012; 23(1):65-69. PMID 21756146.

National Center for Biotechnology Information. PRAME preferentially expressed antigen in melanoma. 2018; https://www.ncbi.nlm.nih.gov/gene/23532.

DermTech. Pigmented Lesion Assay: Non-invasive gene expression analysis of pigmented skin lesions. Performance and Development Notes. 2015; http://dermtech.com/wpcontent/uploads/2015/10/White-Paper- DermTech-MelanomaAssay-.pdf

Gerami P, Yao Z, Polsky D, et al. Development and validation of a noninvasive 2-gene molecular assay for cutaneous melanoma. J Am Acad Dermatol. Jan 2017; 76(1): 114- 120.e2. PMID 27707590

CMS MCD Search