VERMONT

**State of Vermont**
**Department of Vermont Health Access**
280 State Drive, NOB 1 South
Waterbury, VT 05671-1010

Agency of Human Services
[Fax] 802-879-5963
[Fax] 802-879-5963
www.dvha.vermont.gov

## The Department of Vermont Health Access Clinical Criteria

**Subject:** Gene Expression Profiling for Cutaneous Melanoma
**Last Review:** November 8, 2023*
**Past Revisions:** June 13, 2022, November 20, 2020, and October 3, 2019

***Please note: Most current content changes will be highlighted in yellow.**

### Description of Service or Procedure

MyPath® Melanoma assay 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 and accurately distinguishes melanoma from benign nevi.

### Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertain to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

### Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules

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| 7102.2 | Prior Authorization Determination |
| 7405 | Laboratory and Radiology Services |
| 4.101 | Medical Necessity for Covered Services |
| 4.104 | Medicaid Non-Covered Services |
| 4.106 | Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services |

### Coverage Position

MyPath® Melanoma assay may be covered for members:

- When the testing is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont Office of Professional Regulation's website*, Statute, or rule who is knowledgeable

regarding myPath® Melanoma assay and who provides medical care to the member AND

- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: https://sos.vermont.gov/opr/

## Coverage Criteria

Medicaid will follow Medicare's criteria for coverage unless otherwise noted:

Medicaid will provide limited coverage for the MyPath® Melanoma assay 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 dermatopathologist and;
- The specimen is a primary 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) and;
- 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.

Medicare Local Coverage Determination L39479

Considerations: Providers requesting this test should provide pre- and post-test genetic counseling for the member and family, if applicable.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence- based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

## Clinical criteria for repeat service or procedure

One per lesion meeting the criteria above.

## Type of service or procedure not covered (this list may not be all inclusive)

- Gene expression profiling of suspected or established cutaneous melanoma is considered **investigational and not medically necessary.**
- Gene expression profiling of suspected or established uveal melanoma is considered **investigational and not medically necessary.**
- DecisionDx-Melanoma (Castle Biosciences)
- Pigmented Lesion Assay (DermTech)

## Coding guidelines

Please see the Medicaid Portal at http://vtmedicaid.com/#/feeSchedule for fee schedules, code coverage, and applicable requirements.

81479 - Unlisted Molecular Pathology Procedure

## References


Centers for Medicare and Medicaid Services. (n.d.). *Early and Periodic Screening, Diagnostic, and Treatment.* Medicaid.gov. https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html

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