State of Vermont
Department of Vermont Health Access
280 State Drive, NOB 1 South
Waterbury, VT 05671-1010
www.dvha.vermont.gov

Agency of Human Services
[Fax] 802-879-5963
[Fax] 802-879-5963

The Department of Vermont Health Access Clinical Criteria

Subject: myPath® Melanoma Assay
Last Review: June 13, 2022*
Past Revisions: November 20, 2020, and October 3, 2019

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

Description of Service or Procedure

Castle Biosciences (formerly Myriad) 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. For more information visit: https://castletestinfo.com/myPath® -melanoma-diffdx-melanoma/

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertains 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

7102.2	Prior Authorization Determination
7405	Laboratory and Radiology Services
4.101	Medical Necessity for Covered Services
4.104	Medicaid Non-Covered 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 L37923 MolDX: myPath® Melanoma Assay: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=37923&ver=10&keyword=myPath&keywordType=starts&areaId=s55&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

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 that is suspicious for malignancy.

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**

Coding guidelines

81479 - Unlisted Molecular Pathology Procedure

References

Centers for Medicare and Medicaid Services. (n.d). *Early and periodic screening, diagnostic, and treatment.* https://www.medicaid.gov/medicaid/benefits/epsdt/index.html

Centers for Medicare and Medicaid Services. (2021, December 30). *Local coverage determination (LCD): MoIDX: MYPATH® melanoma assay L37923.* https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=37923&ver=10&keyword=myPath®&keywordType=starts&areaId=s55&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

Clarke, L.E., Mabey, B., Flake II, D.D., Meek, S., Cassarino, D.S., Duncan, L.M., High, W.A., Napekoski, K.M., Prieto, V.G., Tetzlaff, M.T., Vitale, P., & Elder, D.E. (2020). Clinical validity of a gene expression signature in diagnostically uncertain neoplasms. *Personalized Medicine, 17*(5), 361-371. https://doi.org/10.2217/pme-2020-0048

Lee, J. & Lian, C. (2019). Molecular Testing for Cutaneous Melanoma. *Archives of Pathology & Laboratory Medicine, 143*, 811-820. doi: 10.5858/ arpa.2018-0038-RA

Reimann, J., Salim, S., Velazquez, E. F., Wang, L., Williams, K. M., Flejter, W. L., Brooke, L., Sunder, S., & Busam, K. J. (2018). Comparison of melanoma gene expression score with histopathology, fluorescence in situ hybridization, and SNP array for the classification of melanocytic neoplasms. *Modern Pathology*, *31*(11), 1733-1743. doi:10.1038/s41379-018-0087-6

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