Cutaneous Melanoma Risk Assessment Algorithmic Tests

I. Cutaneous melanoma risk assessment algorithmic tests are considered **medically necessary** when:

   A. The member has a melanocytic neoplasm that shows at least one ABCDE feature (**a**symmetry, **b**order irregularity, **c**olor variegation, **d**iameter greater than 6 mm, and **e**volution), **AND**

   B. A biopsy is being considered but has not yet been performed, **AND**

   C. The use of the test is limited to a maximum of 2 times per visit.

II. Cutaneous melanoma risk assessment algorithmic tests are considered **investigational** for all other indications.

RATIONALE AND REFERENCES

Cutaneous Melanoma Risk Assessment Algorithmic Tests

National Comprehensive Cancer Network (NCCN): Cutaneous Melanoma (2.2025)

This guideline recommends consideration of “prediagnostic noninvasive patch testing” to help inform decisions regarding biopsy for patients with melanocytic neoplasms that are clinically/dermoscopically suspicious for melanoma (p. ME-12).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous 2.2025
https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf

ECRI Genetic Test Assessment

A recent review completed by ECRI (2023) found evidence for the Pigmented Lesion Assay (PLA) to be somewhat favorable based on the available data demonstrating clinical validity and utility to improve patient outcomes when added to standard of care (p. 1).

ECRI. Pigmented Lesion Assay (DermTech) for Aiding Melanoma Diagnosis. Genetic Test Assessment. Published March 2023.

American Academy of Dermatology

In their 2019 publication, the American Academy of Dermatology states that skin biopsy should be the initial step in establishing a diagnosis of cutaneous melanoma. The article mentions consideration of newer noninvasive techniques, including gene expression analysis (p. 211).

Swetter SM, Tsao H, Bichakjian CK, et al. Guidelines of care for the management of primary cutaneous melanoma. J Am Acad Dermatol. 2019;80(1):208-250. doi:10.1016/j.jaad.2018.08.055

UpToDate

Per UpToDate, “patients with a pigmented lesion that is changing and has additional ABCDE (**a**symmetry, **b**order irregularity, **c**olor variegation, **d**iameter >6 mm, **e**volution) criteria” should be strongly considered for dermatology referral.

Swetter S, Geller A. Melanoma: Clinical features and diagnosis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. Last update Oct 04, 2023.
https://www.uptodate.com/contents/melanoma-clinical-features-and-diagnosis

Centers for Medicare & Medicaid Services (CMS)

Per MolDX: Pigmented Lesion Assay LCD (L38051), this test is used to determine whether a biopsy should be performed. The LCD lists characteristics for the skin lesion that are appropriate for testing, which includes having at least 1 ABCDE criteria.

The LCD also states that “Only 1 test may be used per patient per clinical encounter, in most cases. In roughly 10% of patients, a second test may be indicated for the same clinical encounter. For rare cases where more than 2 tests are indicated in a single clinical encounter, an appeal with supporting documentation may be submitted for additional tests”.

Centers for Medicare & Medicaid Services. MolDX: Pigmented Lesion Assay (LCD L38051). Original effective date: 02/10/2020. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38151

DEFINITIONS

1. **ABCDE feature** is an acronym for examining patients with a lesion that is suspicious for melanoma: **a**symmetry, **b**order irregularity, **c**olor variegation, **d**iameter greater than 6 mm, and **e**volution.
2. **Adjuvant** therapy is a medication (such as chemotherapy or endocrine therapy) given after the surgical removal of a cancerous tumor.
3. **Ductal/NST** is a ductal breast cancer of no special type (NST), meaning the cancer cells have no features that classify them as a specific type of breast cancer when examined by microscope.
4. **Indeterminate cytologic findings** include Bethesda diagnostic category III (atypia/follicular lesion of undetermined significance) or Bethesda diagnostic category IV (follicular neoplasm/suspicion for a follicular neoplasm)