

Evidence-Based Lung Cancer Risk Assessment Algorithmic Tests

- I. Lung cancer risk assessment algorithmic tests with sufficient evidence of clinical validity and utility are considered **medically necessary** when:
 - A. The member is age 40 years or older, **AND**
 - B. The member has a single lung nodule between 8 and 30 mm in diameter, **AND**
 - C. The member has a risk of cancer of 50% or less according to the Mayo risk prediction algorithm, **AND**
 - D. The member does NOT have a diagnosis of cancer (except for nonmelanoma skin cancer) within 5 years of the lung nodule detection.
- II. Lung cancer risk assessment algorithmic tests with sufficient evidence of clinical validity and utility are considered **investigational** for all other indications where clinical validity and utility have not been demonstrated.

REFERENCES

1. Centers for Medicare & Medicaid Services. Medicare Coverage Database: Local Coverage Local Coverage Determination. MoIDX: BDX-XL2 (L37031). Available at: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=37031>
2. Pritchett MA, Sigal B, Bowling MR, Kurman JS, Pitcher T, Springmeyer SC; ORACLE Study Investigators. Assessing a biomarker's ability to reduce invasive procedures in patients with benign lung nodules: Results from the ORACLE study. PLoS One. 2023 Jul 11;18(7):e0287409. doi: 10.1371/journal.pone.0287409. PMID: 37432960; PMCID: PMC10335667.
3. Kheir F, Uribe JP, Cedeno J, Munera G, Patel H, Abdelghani R, Matta A, Benzaquen S, Villalobos R, Majid A. Impact of an integrated classifier using

biomarkers, clinical and imaging factors on clinical decisions making for lung nodules. J Thorac Dis. 2023 Jul 31;15(7):3557-3567. doi: 10.21037/jtd-23-42. Epub 2023 Jun 13. PMID: 37559655; PMCID: PMC10407524.