LungLife AI, Inc.
(the "**Company**" or "**LungLife**")

Medicare Finalises Coverage for Molecular Risk-Stratification Testing of Indeterminate Lung Nodules

LungLife AI (AIM: LLAI), a developer of clinical diagnostic solutions for lung cancer, is pleased to note the publication of the finalized Local Coverage Determination (LCD) titled "Molecular Biomarkers for Risk Stratification of Indeterminate Pulmonary Nodules Following Bronchoscopy" (L39654), issued by the Medicare Administrative Contractor (MAC) Noridian Healthcare Solutions, LLC, which has jurisdiction over LungLife's California laboratory.

The Medicare coverage criteria are effective for medical insurance claims with dates of service on or after September 22, 2024. This enables LungLife to apply for coverage under the LCD in order to receive payment from Medicare. This is a key step towards commercialisation for LungLife, having already received a billing code and established a price of $2,030 per LungLB® test.

The new Medicare coverage policy establishes criteria for molecular tests that aid in the diagnosis of lung cancer in patients with indeterminate pulmonary (lung) nodules. This is crucial for healthcare providers and patients as setting out the circumstances under which Medicare will pay for these services removes a fundamental barrier to adoption by clinicians.

Key points from the LCD include:

- Coverage for molecular tests to aid in the diagnosis of lung cancer in patients with indeterminate pulmonary (lung) nodules who have a non-diagnostic bronchoscopy, provided the other enumerated coverage criteria of the LCDs are satisfied.
- LungLife will be eligible to submit a Technical Assessment for LungLB® under this LCD for post-bronchoscopy indications. Almost half[1] of bronchoscopy biopsies performed are not diagnostic and thus result in a need for follow up activities, accentuating the need for risk stratification testing like LungLB ® in the post-bronchoscopy setting governed by the LCD.
- MolDX[2] is currently considering additional evidence to expand the indications for coverage to pre-bronchoscopy risk stratification. This provides an additional opportunity for LungLife to seek coverage under a potential foundational LCD if they progress with this. Alternatively, LungLife would be in a position to seek an individual coverage determination for this area.

Fundamental components for commercialisation:

There are three fundamental reimbursement components for commercialisation of LungLB®: securing a designated billing code, establishing a price, and obtaining coverage. We have made strong progress across each of these as follows:

- A unique billing code allows LungLife to accurately bill for and receive reimbursement from insurance payers, including Medicare and private insurers. LungLife was assigned CPT code 0317U in January 2022.
- Medicare established a national price of $2,030 per test for LungLB®, effective in January 2023.
- Obtaining coverage from public and private payers is the next crucial step for LungLife. Following the publication of the LCD, we plan to submit a Technical Assessment for coverage under the LCD in order to receive payment from Medicare. This Foundational LCD provides a clear pathway for LungLife to pursue Medicare coverage with MolDX and is generally less time intensive than obtaining a new test specific LCD.

The full publication of the LCD can be found here. Molecular Biomarkers for Risk Stratification of Indeterminate Pulmonary Nodules Following Bronchoscopy.

Commenting, Paul Pagano, Chief Executive Officer of LungLife, said:
"Having a Local Coverage Determination (LCD) for risk stratification testing of indeterminate lung nodules represents a key opportunity for our company. It enables us to progress to the next stage of commercialisation by providing a clear pathway to make our innovative LungLB® test more accessible and reimbursable under Medicare. This supports our commitment to enabling 80% of lung cancer to be detected early."

For further information please contact:

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Notes
1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7729592/
2. The MolDX Program was developed in 2011 to identify and establish coverage and reimbursement for molecular

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About LungLife

LungLife AI is a developer of clinical diagnostic solutions designed to make a significant impact in the early detection of lung cancer, the deadliest cancer globally. Using a minimally invasive blood draw, the Company's LungLB® test is designed to deliver additional information to clinicians who are evaluating indeterminate lung nodules. For more information visit www.lunglifeai.com

Our Purpose is to be a driving force in the early detection to lung cancer. And our Vision is to invert the 20:80 ratio such that in years to come at least 80% of lung cancer is detected early.

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