

## ASX ANNOUNCEMENT

# Lumos Secures Further Key U.S. Reimbursement Milestones for FebriDx®

# **Key Highlights**

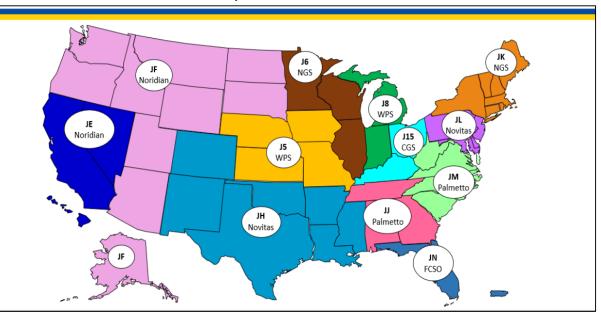
- Lumos has secured reimbursement coverage for FebriDx<sup>®</sup> with two Medicare Administration Contractors (MACs) at US\$41.38 per test effective April 2025.
- Medicare is an important part of U.S. healthcare reimbursement, comprising 20%-24% of the U.S. reimbursement payor mix. 7 MACs support reimbursement processing across the U.S.
- Negotiations continue with the remaining five MACs, with discussions well progressed with three of the five.
- Medicare adoption often sets a precedent for reimbursement acceptance by private insurance payors.

**MELBOURNE, Australia (17 April 2025)** – Lumos Diagnostics (ASX: LDX), ("Lumos" or the "Company") a leader in rapid, point-of-care diagnostic technologies, is pleased to announce a series of significant milestones in the U.S. reimbursement pathway for its U.S. manufactured FebriDx<sup>®</sup> test, a rapid point-of-care diagnostic designed to differentiate between bacterial and non-bacterial acute respiratory infections in around 10 minutes.

As previously announced (*ASX: 5 December 2024*), from 1 January 2025, the Centers for Medicare & Medicaid Services (CMS) officially included FebriDx in the 2025 Clinical Laboratory Fee Schedule (CLFS) under Proprietary Laboratory Analyses (PLA) Code #0442U, with a national reimbursement rate of US\$41.38 per test. This reimbursement decision affirmed the test's clinical value and economic viability, marking a major step toward widespread U.S. adoption.

Securing the reimbursement rate from CMS via PLA Code 0442U was a critical first step. Payment (coverage) of the PLA Code to healthcare providers by the payors (Medicare and private insurance) is not automatic and must be secured. Lumos has executed a strategy of seeking comprehensive Medicare coverage for FebriDx<sup>®</sup>. Medicare comprises approximately 20%–24% of the U.S. payor mix and often sets a precedent for private payors. Lumos has now engaged with all seven Medicare Administrative Contractors (MACs) and is seeing positive early momentum:

- Effective from April 2025, FebriDx<sup>®</sup> has been added to the Medicare Fee Schedule in the Palmetto and Novitas regions at US\$41.38 per test.
- Discussions are well progressed with Noridian, WPS, and CGS regions, with next steps underway to formalise inclusion to their Medicare Fee Schedule.



Map of U.S. MAC Jurisdictions

Reimbursement coverage, particularly from private payors traditionally follows real-world utilisation. Lumos' field teams are actively supporting claim appeals to help them secure insurance coverage by assisting with medical necessity documentation and capturing clinician feedback. This on-the-ground effort is expected to drive continued adoption and to broaden coverage throughout 2025 and into 2026.

Importantly, the reimbursement pathway already encompasses both Moderately Complex and CLIA-Waived settings. Should Lumos be successful with having FebriDx<sup>®</sup> CLIA waived, this will in time allow FebriDx<sup>®</sup> to seamlessly transition across the two testing environments, without repeating the reimbursement process.

As Medicare adoption increases, Lumos expects the positive cascading effect to influence the decision of private insurers to consider adopting coverage, further validating FebriDx's role in improving clinical outcomes, reducing unnecessary antibiotic prescriptions, and enhancing patient care.

Commenting on the announcement, Doug Ward, Managing Director of Lumos Diagnostics said: *"It is extremely pleasing to achieve some early wins with two of the 7 U.S. Medicare Administration Contractors. This is an important and critical step in building the reimbursement framework to support clinical adoption for FebriDx*<sup>®</sup>.

Manufactured proudly in the United States, FebriDx<sup>®</sup> is not only addressing a critical clinical need in primary care, urgent care, and emergency medicine, but it is also supporting American jobs and innovation in point-of-care diagnostics. Lumos looks forward to the day that FebriDx<sup>®</sup> has broad U.S. reimbursement coverage across both public and private insurers and the team is working to deliver on that objective."

#### -Ends-

#### This announcement has been approved by the Lumos Disclosure Committee.

#### **About Lumos Diagnostics**

Lumos Diagnostics specializes in rapid and complete point-of-care diagnostic test technology to help healthcare professionals more accurately diagnose and manage medical conditions. Lumos offers customized assay development and manufacturing services for point-of-care tests and proprietary digital reader platforms. Lumos also directly develops, manufactures, and commercializes novel Lumos-branded point-of-care tests that target infectious and inflammatory diseases.

For more information visit lumosdiagnostics.com.

### **Forward-Looking Statements**

This announcement contains forward-looking statements, including references to forecasts. Forwardlooking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions, and other important factors, many of which are beyond Lumos' control and speak only as of the date of this announcement. Readers are cautioned not to place undue reliance on forward-looking statements.

# Media Contact:

Haley Chartres – Australia H^CK Director haley@hck.digital +61 (0) 423 139 163

### **Investor Contact:**

George Kopsiaftis IR Department ir@lumosdiagnostics.com +61 409 392 687

### **Company Registered Office:**

Lumos Diagnostics Holdings Ltd Level 4, 100 Albert Rd South Melbourne, VIC 3205, Australia +61 3 9087 1598