

4DMedical gains U.S. CMS reimbursement for CT LVAS™

9 May 2024

Highlights

- The AMA CPT Editorial Panel has notified 4DMedical that it may utilise two existing Category III CPT codes for the reimbursement of CT LVAS™ technology
- From today, CT LVAS™ scans conducted in a U.S. hospital outpatient facility for Medicare beneficiaries may be billed to Centers for Medicare & Medicaid Services (CMS) with a reimbursement of US\$650.50
- CT LVAS™ now has a benchmark payment level set for hospital outpatient procedures, serving as a guide for private health insurers in determining their pricing levels

Melbourne, Australia, 9 May 2024: Respiratory imaging technology company 4DMedical Limited (ASX:4DX, “4DMedical”, or the “Company”) today announces the inclusion of 4DMedical’s CT LVAS™ technology to existing Category III Current Procedural Terminology (CPT) codes with associated access to the U.S. Centers for Medicare & Medicaid Services (CMS) annual, final payment rates for hospital outpatient-based services, effective immediately.

Widened access to CT LVAS™ for patients at Medicare-funded facilities

The American Medical Association (AMA) CPT Editorial Panel Review has informed 4DMedical of its determination that the application for an individual code for CT LVAS™ was not required. After review and consideration of the information provided by 4DMedical, the CPT panel, consisting of 14 Medical societies inclusive of four Radiology societies, identified two existing Category III CPT codes (0721T and 0722T) that can be used for reimbursement of CT LVAS™.

These existing codes already attract a reimbursement payment of US\$650.50 per scan under the 2024 Medicare rulings for eligible facilities. As the codes are already in place with a reimbursement payment attached, CT LVAS™ scans conducted in a U.S. hospital outpatient facility for Medicare beneficiaries may be billed to CMS from today.

CMS reimbursement provides access to CT LVAS™ at over 4,000 Medicare-certified hospitals across the U.S., ensuring that CT LVAS™ technology, which can be performed on existing CT scanners, is available to Medicare beneficiaries suffering from lung disease. This provides a funding source for providers of the technology beyond full out-of-pocket payment. Importantly, this benchmark payment level, set for hospital outpatient procedures, serves as a guide for private health insurers in determining their pricing levels, typically at a much higher rate.

Centers for Medicare & Medicaid Services (CMS)

CMS is the federal agency providing health coverage through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. Medicare is an important public health insurance scheme for U.S. adults aged 65 years and over, with an estimated 66 million people enrolled in the program.

CMS has various payment methodologies and fee schedules applicable to procedures, services and products based upon where services are rendered. Medicare fee schedules include the Physician Fee Schedule (MPFS) which applies to services rendered in office-based settings; the Inpatient Prospective



Payment System (IPPS) which applies to hospital services rendered in the inpatient setting; and the Hospital Outpatient Prospective Payment System (HOPPS) which applies to hospital outpatient services.

The Company now has reimbursement for both CT LVAS™ and XV LVAS®, having last year successfully established a new and distinct AMA Category III CPT code identifying the use of XV LVAS® by healthcare providers and payers at the CMS rate of US\$299.

4DMedical MD/CEO and Founder Andreas Fouras said:

I am very excited by this progress in the commercialisation of our technology, and the positive impact this CPT code and associated reimbursement will have upon doctors and their patients. An identified Medicare reimbursement of US\$650.50 per scan provides direct access to CT LVAS™ for the 66 million Americans enrolled in Medicare.

The routine use of chest CT in the clinical work up of respiratory patients, combined with the recognised value of our scan, makes the AMA's decision one of the most significant breakthroughs to date in our history. Furthermore, I believe this decision helps to establish the appropriate pricing of our technology within the VA.

I am excited to note that this news comes less than 6 months following the FDA clearance of CT LVAS™, demonstrating growing strength in our team and our reputation with key organisations such as the AMA and associated medical societies. This bodes well for continued success with reimbursement of future products such as IQ-UIP and CT:VQ, both expected to be filed with the FDA in 2024.

—ENDS—

Authorised by the 4DMedical Board of Directors.

Contacts

Corporate

Chief Financial Officer

Simon Glover

sglover@4dmedical.com

Administration

Company Secretary

Naomi Lawrie

companysecretary@4dmedical.com

Media Enquiries

Director of Market Development
and Communication

Hayley Willis

4Dmedia@4dmedical.com

About 4DMedical

4DMedical Limited (ASX:4DX) is a global medical technology company that has created a step change in the capacity to accurately and quickly understand the lung function of patients with respiratory diseases.

Through its flagship patented XV Technology®, 4DMedical enables physicians to understand regional airflow in the lungs and identify respiratory deficiencies earlier and with greater sensitivity as they breathe. This technology powers 4DMedical's FDA-cleared XV Lung Ventilation Analysis Software (XV LVAS®) – the first modality to dynamically quantify ventilation throughout the lungs, and its Computed Tomography-enabled counterpart software, CT LVAS™.



XV LVAS® and CT LVAS™ reports are prepared using 4DMedical's Software as a Service delivery model using existing hospital imaging equipment or the Company's revolutionary XV Scanner.

In December 2023, 4DMedical acquired Imbio, a leader in artificial intelligence medical imaging solutions for chronic lung and cardiothoracic diseases. Imbio's regulatory-cleared solutions transform the way patients are discovered, diagnosed, and treated, enabling physician productivity and more personalised care for patients.

To learn more, please visit www.4dmedical.com.