

U.S. Centers for Medicare & Medicaid Services (CMS) approves reimbursement for 4DMedical

13 November 2023

Highlights

- U.S. Centers for Medicare & Medicaid Services (CMS) assigns US\$299 as reimbursement benefit for XV LVAS®
- From 1 January 2024, XV LVAS® scans conducted in a U.S. hospital outpatient facility for Medicare patients can be billed to CMS
- XV 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
- CMS reimbursement will accelerate utilisation of XV LVAS® under 4DMedical's existing Category III CPT code, a key criterion for the AMA when considering granting a Category I CPT code

Melbourne, Australia, 13 November 2023: Respiratory imaging technology company 4DMedical Limited (ASX:4DX, "4DMedical", or the "Company") today announces the inclusion of 4DMedical's XV LVAS® procedure to the U.S. Centers for Medicare & Medicaid Services (CMS) annual, final payment rates for hospital outpatient-based services, effective 1 January 2024.

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 reimbursement decision will have upon doctors and their patients. Achieving a Medicare reimbursement of US\$299 per scan is a major milestone in our progress to secure reimbursement across the entire U.S. healthcare system and meaningfully removes a barrier to broader adoption across the large network of facilities providing healthcare to the 65 million Americans enrolled in Medicare. This ruling will lead to accelerated uptake of XV LVAS®, which in turn will support our pursuit of a Category I CPT code.

Centers for Medicare & Medicaid Services (CMS)

Centers for Medicare & Medicaid Services (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; as of 1 March 2023, there were 65.7m 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.

All items and services paid under HOPPS are assigned to payment groups called Ambulatory Payment Classifications (APCs), grouping together items and services that are similar clinically and in terms of

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resource use. CMS releases annual public updates regarding changes the agency is planning to make to the payment schedule for the coming calendar year.

Last year 4DMedical was successful in establishing a new and distinct AMA Category III CPT code identifying the use of XV LVAS[®] by healthcare providers and payers. Category III CPT codes are a set of temporary codes for new and emerging technologies that are created for data collection in substantiating the widespread usage of a technology. CMS has now included assignment of payment levels to the CPT III codes for XV LVAS[®] in the 2024 HOPPS Proposed Rule.

Widened access to XV LVAS[®] for patients at Medicare funded facilities

After review and consideration of the information and public comment provided by 4DMedical, CMS accepted the reimbursement request and finalised assignment of the Category III CPT code for XV LVAS[®] to the rate of US\$299 per scan.

CMS payment policy changes affect care delivery at over 4,000 Medicare-certified hospitals across the country. This significant and positive change ensures that XV LVAS[®] is available to Medicare patients afflicted with lung disease and provides a funding source for providers of the technology beyond full out-of-pocket payment.

–ENDS–

Authorised by the 4DMedical Board of Directors.

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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 clinical imaging equipment or the Company's revolutionary XV Scanner.

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

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