

4DMedical receives TGA approval for CT:VQ™ in Australia

26 June 2026

Highlights

- CT:VQ™ approved by the Therapeutic Goods Administration (TGA) and included in the Australian Register of Therapeutic Goods (ARTG), enabling commercial deployment across Australia
- Australia becomes the latest approved market for CT:VQ™, which now holds regulatory clearance across the United States, European Union, United Kingdom, Canada and New Zealand
- Each additional regulatory approval strengthens the clinical, regulatory and reimbursement foundation for CT:VQ™ to become the new standard for functional lung assessment globally
- Australia has one of the highest CT scanner densities in the world, supporting rapid nationwide deployment, including regional locations that lack nuclear medicine services
- CT:VQ™ is a software-only, non-contrast, ventilation-perfusion solution that enables functional lung imaging using existing CT infrastructure
- The recent commercial agreement with SimonMed Imaging demonstrates CT:VQ™'s applicability in high-volume community imaging settings and provides a reference model for Australian deployment
- Progressing a Medical Services Advisory Committee (MSAC) submission to secure future Medicare Benefits Schedule (MBS) reimbursement

Melbourne, Australia, 26 June 2026: 4DMedical Limited (ASX: 4DX, “4DMedical” or the “Company”), a global leader in respiratory imaging technology, today announces that its non-contrast ventilation-perfusion imaging solution, CT:VQ™, has been approved by the Therapeutic Goods Administration (TGA) and included in the Australian Register of Therapeutic Goods (ARTG), enabling commercial deployment across Australia.

This approval represents a significant regulatory milestone and positions CT:VQ™ for routine clinical use across Australia's healthcare system. CT:VQ™ enables radiologists and referring clinicians to obtain regional ventilation and perfusion information directly from standard non-contrast chest CT scans, without injections, contrast agents, radiotracers or nuclear medicine infrastructure.

Building a global footprint

Australia becomes the latest approved market for CT:VQ™, which now holds regulatory clearance across the United States, European Union, United Kingdom, Canada and New Zealand.

Each new approval extends beyond the immediate commercial opportunity in that market. Collectively, these approvals strengthen the clinical evidence base, establish reimbursement precedent, increase physician familiarity, and deepen regulatory confidence in CT:VQ™. Together, these factors build the foundation for CT:VQ™ to become the new standard for functional lung assessment globally.



	FDA (USA)	CE Mark (EU)	TGA (AU)	CMDR (Canada)	MHRA (UK)	Medsafe (NZ)	ANVISA (Brazil)
CT LVAS™	✓	✓	✓	✓		✓	
CT:VQ™	✓	✓	✓	✓	✓	✓	
IQ-UIP™	✓			Submitted			
LDA™	✓	✓	✓	✓	✓		✓
Lung Texture		✓	✓	✓	✓		✓
CAC™	✓	✓	Submitted	✓			✓
PHA™ RV/LV	✓	✓	✓				✓
XV LVAS®	✓	✓	✓			✓	

Regulatory status of each 4DMedical product by jurisdiction.

Momentum has been particularly strong in the United States following FDA clearance in September 2025. CT:VQ™ has since been deployed across leading Academic Medical Centres including Stanford, Cleveland Clinic, UC San Diego Health, University of Chicago Medicine and University of Miami, with evaluation well-progressed at Mayo Clinic.

Momentum has also expanded into community-based imaging through the Company's recently announced commercial agreement with SimonMed Imaging, one of the largest and most influential outpatient radiology providers in the United States. The agreement demonstrates CT:VQ™'s applicability in high-volume outpatient radiology environments and provides a strong reference model for broader deployment in Australia.

Australian clinicians have closely followed CT:VQ™'s progress following FDA clearance and subsequent U.S. deployments, with multiple sites engaging with the Company in anticipation of Australian approval. With TGA approval now secured, those discussions can progress to implementation.

Australia's exceptional CT infrastructure supports nationwide access

CT:VQ™ eliminates the traditional dependence on radiotracers, specialised cameras, and nuclear medicine infrastructure, enabling broader access to functional lung imaging across metropolitan, regional and rural communities.

Australia is uniquely positioned for rapid adoption due to its extensive CT infrastructure. With more than 74 CT scanners per million people, Australia ranks among the highest CT-utilisation markets globally and has the second-highest reported CT scanner density worldwide.

This extensive CT footprint enables CT:VQ™ to become one of Australia's most accessible functional lung imaging modalities, particularly for:

- Regional and rural communities, where nuclear medicine services may be limited or unavailable;
- Smaller hospitals and imaging centres that possess CT scanners but lack nuclear medicine equipment or specialist staffing;

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- Health systems seeking to reduce patient exposure to inhaled and injected radioisotopes, while minimising associated logistical burden; and
- Health systems seeking a scalable, software-based alternative to traditional ventilation-perfusion imaging, enabling more efficient use of nuclear imaging capacity for advanced procedures such as oncologic theranostics.

Pathway to Medicare reimbursement

With TGA approval now secured, 4DMedical will commence preparation of an application to the Medical Services Advisory Committee (MSAC) to pursue Medicare Benefits Schedule (MBS) reimbursement for CT:VQ™.

This submission will incorporate clinical evidence, health-economic modelling, and real-world utilisation data generated through Australian deployment. The Company believes that the combination of international regulatory validation, growing clinical adoption, Australia's extensive CT infrastructure and the health-system efficiencies enabled by a non-contrast ventilation-perfusion solution will provide a compelling basis for reimbursement consideration.

4DMedical MD/CEO and Founder Andreas Fouras said:

TGA approval clears the way for CT:VQ™ to be deployed across Australia and marks a landmark moment for respiratory diagnostics in our home market.

Australia is the latest approved market for CT:VQ™, supporting our global commercial expansion and reinforcing the growing international validation of our technology. Every market we enter contributes to a larger strategic objective. Each approval strengthens the clinical evidence, reimbursement precedent and credibility that together build the case for CT:VQ™ to become a new standard for functional lung assessment worldwide.

As the first non-contrast, CT-based ventilation-perfusion solution, CT:VQ™ expands access to functional lung imaging while leveraging existing healthcare infrastructure. Australia's exceptional CT scanner density makes it one of the most scalable markets we have entered.

Our momentum in the United States continues to build. In just a matter of months, CT:VQ™ has been deployed across leading health systems including Stanford, Cleveland Clinic, UCSD, University of Chicago and University of Miami, with evaluation well-progressed at Mayo Clinic. Our agreement with SimonMed Imaging further demonstrates the technology's applicability in high-volume community imaging settings.

With TGA approval secured and a reimbursement pathway ahead, 2026 continues to be a defining year for 4DMedical as we expand access to next-generation respiratory imaging for patients, clinicians and health systems around the world.

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About 4DMedical

4DMedical Limited (ASX:4DX) is a global medical technology company revolutionising respiratory care with advanced imaging and artificial intelligence. Its patented **XV Technology**[®] transforms standard scans into rich, functional insights that allow physicians to detect, diagnose, and monitor lung disease earlier and with greater precision.

4DMedical's expanding software portfolio includes the FDA-cleared **XV Lung Ventilation Analysis Software (XV LVAS[®])**, **CT LVAS[™]**, and the ground-breaking **CT:VQ[™]** solution designed to set new benchmarks in cardiothoracic imaging by combining ventilation and perfusion analysis.

Delivered seamlessly through a Software-as-a-Service (SaaS) model, 4DMedical's solutions integrate into existing hospital infrastructure, enhancing physician productivity and enabling more personalised patient care. With the addition of advanced AI capabilities from its 2023 acquisition of **Imbio** and 2026 acquisition of **contextflow**, 4DMedical continues to push the boundaries of medical imaging to redefine how respiratory disease is understood and treated worldwide.

Learn more at www.4dmedical.com

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