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Thursday, 27 August 2026

US Medicare Billing Code Secured for NextLevel Speech Generating Devices, US Sales to Start

Highlights

- Final US market access prerequisite cleared with first revenues targeted for September 2026
- US Medicare PDAC coding verification granted for two UnoTouch Omni models, with Control Bionics Inc. named as manufacturer.
- Devices assigned HCPS code E2510, the highest allowable among Medicare's speech generating device base codes with a fee schedule allowable of up to US$9,645.69 per device per new device across the US.
- Verification was the final prerequisite to commencing US sales of the UnoTouch Omni range. Claims may now be billed to all four Durable Medical Equipment Medicare Administrative Contractors (DME MACs).
- Non-binding Letter of Intent in place with a US launch customer for up to 1,000 devices in the first 12 months, with a US$100,000 advance payment received.

Control Bionics Limited (ASX: CBL) ("Control Bionics" or "the Company") advises its US subsidiary, Control Bionics Inc., has received Healthcare Common Procedure Coding System (HCPCS) coding verification from the Pricing, Data Analysis and Coding (PDAC) Contractor for the UnoTouch Omni range of Apple iOS-based speech generating devices (SGDs), commercialised under the Company's exclusive licence agreement with NextLevel Assistive Technology.

The UnoTouch Omni range is commercialised under the Company's exclusive licence agreement with NextLevel Assistive Technology, announced on 26 February 2026. Speech generating devices restore a voice to people living with conditions that impair or take away speech, including motor neurone disease (ALS), cerebral palsy, autism and stroke. With coding verification granted, the UnoTouch Omni range can now be funded through the US reimbursement system, clearing the way for US sales to commence.

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What PDAC coding verification means

Since 1 June 2016, the only products that may be billed to Medicare (and by extension Commercial Insurers) under HCPCS code E2510 are those for which the PDAC Contractor has issued written coding verification and which appear on the Product Classification List. Without that verification, a claim submitted under E2510 is denied as incorrectly coded.

E2510 is defined as a speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access. It is the broadest and highest-value code in the SGD family, reflecting devices capable of both multiple message-construction methods and multiple access methods.

Coding verification therefore removes the last regulatory barrier between the UnoTouch Omni range and the US reimbursement system. It allows Control Bionics' distribution partners to submit claims for the devices through their existing Medicare, Medicaid and private payer billing workflows, in the same way they do for the Company's NeuroNode product.

Reimbursement value

Under the 2026 Medicare DMEPOS fee schedule, E2510 carries a national allowable of up to US$9,645.69 for a new device purchase (NU modifier, non-rural rate), applicable across all US states. Medicaid programs and many private payers benchmark their own SGD schedules to the Medicare rate.

It is important to note that the fee schedule allowable is the amount payable to the accredited durable medical equipment supplier that dispenses the device to the patient. It is *not* Control Bionics' revenue per unit. Under the NextLevel licence, Control Bionics sells to its distribution partners on wholesale terms and receives a fixed per-device contribution margin, with NextLevel funding all device tooling and manufacturing.

Market context

Speech generating devices are funded in the United States through Medicare Part B, state Medicaid programs (including as a mandatory benefit for children under the Early and Periodic Screening, Diagnostic and Treatment provisions), private insurance, education agencies and the Veterans Health Administration.

As previously disclosed, the Company estimates annual US SGD volumes at approximately 55,000 to 65,000 units, of which tablet-based devices account for 60–70% of new prescriptions, representing an iOS-based segment estimated at US$100–150 million annually. Control Bionics' initial contemplated volumes of 1,000–1,500 devices per annum represent a small share of that addressable market, and thus a good opportunity for further market share growth.

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Route to market

Consistent with the strategy set out when the NextLevel licence was announced, Control Bionics will not pursue a direct-to-consumer or retail model for the UnoTouch Omni range. The devices will be supplied wholesale to the Company's established US distribution partners, who hold the payer contracts, accreditation and clinical service infrastructure required to dispense funded devices at scale.

This approach requires no incremental capital investment or manufacturing risk from Control Bionics.

Commentary

Jeremy Steele, Chief Executive Officer and Managing Director, said:

> *"PDAC coding verification is the gate every speech generating device must pass before it can be funded in the US. Our distribution partners can bill these devices through the workflows they already run every day. More Americans who cannot speak will have access to a proven device that helps give them a voice.*
>
> *"With coding now resolved, our focus is on supporting our launch customer's rollout plans, with first revenue targeted for September."*

Authorisation

This announcement has been authorised for release by the CEO of Control Bionics Limited.

For further information

Jeremy Steele
CEO and Managing Director
jsteele@controlbionics.com

Brett Crowley
Company Secretary
brettcrowley@controlbionics.com

About Control Bionics

Control Bionics Limited is a neurotechnology company commercialising objective, non-invasive neural-signal technology proven in clinical environments and built to scale across multiple markets. Its neural-signal platform captures the body's physiological signals, including the electrical activity generated by muscles, with medical-grade precision and converts them into measurable, decision-ready outcomes. A single underlying technology platform serves four applications: Performance, Rehabilitation, Research & Data, and Assistive Communication. The technology has historically been deployed in assistive communication

and is now being extended into sports performance, rehabilitation, medical research, platform partnerships and broader human-computer interface applications. Control Bionics' technology does not require surgery or implantation, and holds regulatory clearances in the US, Australia and Europe. The Company is also a registered NDIS provider in Australia.

About NextLevel Assistive Technology

NextLevel Assistive Technology is a US-based developer of iOS-based speech generating device hardware. It designs and manufactures the UnoTouch Omni range, which Control Bionics assembles and distributes in the United States under an exclusive licence, with NextLevel retaining device IP and funding all tooling and manufacturing.

Forward-looking statements

This announcement contains forward-looking statements, including statements regarding expected timing of first revenue, contemplated device volumes and market size. These statements are based on the Company's current expectations and assumptions and are subject to risks and uncertainties, including conversion of the non-binding Letter of Intent into binding orders, distributor purchasing decisions, payer coverage and claims adjudication outcomes, and manufacturing and supply timing. Actual results may differ materially. The Company does not undertake to update forward-looking statements except as required by law.

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