

2 September 2025

ASX Announcement

U.S. Medicare Reimbursement Proposal

PolyNovo Limited (**PolyNovo or the Company**) outlines in this announcement the impact and opportunity for PolyNovo of the proposed changes to U.S. Medicare Reimbursement for **outpatient** wound care as written in The Australian on 31 August 2025 article titled “*Aussie medtech’s unlikely boost from RFK health crackdown.*”

Current System

Under the existing reimbursement model, physicians are paid a percentage of the price for each skin substitute used in **outpatient** wound care. This has dis-incentivised the selection of lower priced product as it reduces the physician/surgeon payment with a decrease in product cost. As a result, the market has favoured expensive products—driving significant Medicare outlays and making it harder for cost-effective options to compete.

The New York Times reported “spending on skin substitutes exceeded \$10 billion in 2024, more than double the figure in 2023”

Proposed Change

However, in July 2025 the New York Times reported that the industry was caught off guard when the Trump administration proposed a new plan to lower reimbursements to a fraction of what some companies currently earn. The Centers for Medicare & Medicaid Services (CMS) proposed flat reimbursement for outpatient skin substitutes of **USD \$806 per square inch**. This fundamental change is designed to remove the economic incentive for surgeons to use higher-cost products and to create a more level, value-oriented market.

“CMS currently treats skin substitutes as biologicals for the purposes of Medicare payment, which can reach as high as \$2,000 per square inch. CMS is proposing to pay for skin substitutes as incident-to supplies, a change expected to reduce spending on these products by nearly 90%. These proposed savings would not come at the expense of patient access or quality of care... This will save billions for Medicare and taxpayers and incentivize the use of products with the most clinical evidence of success.”

— CMS Press Release, July 2025

Implications for PolyNovo

- 1. Sustained Margins:** NovoSorb® BTM and MTX products are profitable under the proposed flat rate.
- 2. Enhanced Competitiveness:** The removal of price-based incentives may reduce the presence of higher-cost competitors, benefiting clinically robust, cost-effective products.
- 3. Growth Potential:** Physicians' decision-making will increasingly focus on proven clinical outcomes, where PolyNovo products compete strongly.

Acting CEO Dr Robyn Elliott said: *“The majority of PolyNovo’s current business has to date been inpatient product application. Outpatient product application, the focus of the CMS proposed changes, is a significant potential growth area for PolyNovo’s products. We are currently assessing the optimal commercial model for accessing this market opportunity.”*

Chairman David Williams said: *“PolyNovo is well positioned to benefit from changes to the U.S. outpatient reimbursement landscape. We have always placed importance on quality as well as value and the proposed new flat reimbursement will suit our value-oriented offering. There are a number of things to play out before it is clear what the full benefit for PolyNovo will be with plastic surgeons and podiatrists, but I am excited by the possibilities. In particular, we are very keen to bring our technology to help American servicemen and women, veterans and others with chronic wounds exacerbated by diabetes.”*

The CMS proposal is currently under consultation, with a decision expected in November for a 1 January 2026 start. PolyNovo will monitor developments and update shareholders as appropriate.

This announcement has been authorised by the Board of Directors of PolyNovo Limited.

About PolyNovo®

PolyNovo is a disruptive ASX 200 medical technology company, based in Melbourne, Australia. Its products simplify management of acute complex wounds, redefining healing with meaningfully differentiated patient outcomes across multiple wound etiologies. After treating 70,000+ patients across 46 countries, the company is investing for growth with new products, indications, and markets. For more information see polynovo.com.

About NovoSorb®

NovoSorb BTM is a dermal scaffold for the regeneration of the dermis when lost through surgery, trauma or burn. NovoSorb is a novel range of bio-resorbable polymers that can be produced in many formats including film, fibre, foam, and coatings. NovoSorb's unique properties provide excellent biocompatibility, control over physical properties, and a programmable bio-resorption profile.

About NovoSorb MTX®

NovoSorb MTX leverages the technology platform underpinning the clinical success of NovoSorb BTM, but **without a sealing membrane**, and is designed to support natural wound healing, especially for wounds that are highly exudative or those with an uneven wound bed. The product was developed to satisfy clinician demand for a product for use in indications where the sealing membrane is not required.

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