

## SYMPHONY<sup>TM</sup> - OUTPATIENT REIMBURSEMENT UPDATE

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The US Centers for Medicaid & Medicare Services (CMS) has released an important update on the reimbursement of outpatient skin substitute grafts/cellular and tissue-based products (Skin Substitutes).

AROA is pleased to announce that patients and clinicians will continue to have access to AROA's Symphony products to treat diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) until at least the end of 2026.

The update states that:

- Medicare Administrative Contractors (MACs) will issue updated Final Local Coverage Determinations (LCDs) relating to the reimbursement of Skin Substitutes for the treatment of DFUs and VLUs - effective 1 January 2026.
- CMS has classified Skin Substitutes into three categories:
  - **Covered:** Products that meet clinical evidence thresholds and will be covered by Medicare from January 1, 2026.
  - **Discretionary:** Products that, for the next 12 months, can be paid for on a case-by-case basis at the MACs' discretion, while the manufacturers complete clinical studies. AROA's Symphony product is in this category.
  - **Non-covered:** Products for which adequate evidence has not been provided (or for which there is no evidence of ongoing clinical research) and will not be covered by Medicare.
- The MACs will review evidence received by December 31, 2026, for "discretionary" products, and are expected to release updated LCDs in early 2027.

Although the CMS update also mentions Myriad<sup>TM</sup> products, the primary market for Myriad is the hospital inpatient setting, which falls under a different reimbursement framework.

### ***Next steps for Symphony outpatient reimbursement***

The establishment of the three categories underscores the critical importance of robust clinical evidence to demonstrate the efficacy of outpatient wound care products.

AROA has completed its Randomised Control Trial (RCT) for Symphony and expects the study to be published in 2026. The Company plans to provide the study findings to the MACs well ahead of the December 31, 2026, deadline.

AROA CEO Brian Ward says: "The recent announcement by CMS shows confidence in Symphony and is a positive step towards securing CMS coverage. We expect the data from our Symphony RCT to provide the necessary clinical evidence to support CMS coverage and are pleased that clinicians and patients will have continued access to Symphony while our clinical evidence is reviewed."

The update can be found [here](#).

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**Authorised on behalf of the Aroa Biosurgery Board of Directors by Brian Ward, CEO.**

**Contact**

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**About AROA™**

Aroa Biosurgery is a soft-tissue regeneration company committed to 'unlocking regenerative healing for *everybody*'.

We develop, manufacture, sell and distribute medical and surgical products to improve healing in complex wounds and soft tissue reconstruction. Our products are developed from a proprietary AROA ECM™ technology platform, a novel extracellular matrix bioscaffold derived from ovine (sheep) forestomach.

Over 7 million AROA devices have been used globally in a range of procedures to date, with distribution into our key market of the United States via our direct sales force and our partner TELABio, Inc.

Founded in 2008, AROA is headquartered in Auckland, New Zealand and is listed on the Australian Securities Exchange (ASX: ARX). [www.aroa.com](http://www.aroa.com)

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