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AOTI, INC. (the "Company" or "Group" or "AOTI")

TWO₂[®] therapy to be included in NHS supply chain framework agreement for 2025

Peer-reviewed health economic study shows TWO₂[®] therapy would significantly lower overall diabetic foot care costs for NHS in England

AOTI, INC. (AIM: AOTI), a medical technology group focused on the durable healing of wounds and the prevention of amputations, announces its multi-modality Topical Wound Oxygen (TWO₂[®]) therapy has been awarded inclusion by NHS Supply Chain to the framework agreement for Advanced Wound Care 2025, which becomes effective on 1st September 2025.

This follows the recent publication of the results from a new health economic (HE) study in the *Journal of Diabetic Complications*¹ and authored by a team of leading UK-based health economists and diabetic foot clinical experts, demonstrating that adoption of AOTI's unique TWO₂[®] therapy within the National Health Service (NHS) in England, UK, would significantly lower overall diabetic foot care costs.

In England, the estimated cost of diabetic foot disease is almost 1% of the entire annual NHS budget, which is forecast to reach £192 billion in 2025,^{2,3} with non-healing ulcers being the major cost driver. Up to one third of diabetics will suffer from a diabetic foot ulcer (DFU) in their lifetime, which are the leading cause of morbidity and lower extremity amputations in the diabetic population. It is estimated that approximately 66% of DFUs do not heal within a year, and approximately 50% become infected, which can lead to life-threatening infections, hospitalisations and limb amputation.⁴

Dr. Mike Griffiths, Chief Executive Officer & President of AOTI, commented: "It is exciting to see acknowledgement of the clinical and health economic benefits delivered by our unique cyclical-pressure TWO2[®] therapy with its inclusion in the new framework agreement for Advanced Wound Care. Once implemented patients across England will have easier access to our proven limb saving outcomes and the NHS can start to realise substantial cost savings. These benefits are driven by significantly reduced wound recurrence, hospitalisations and amputations, all of which translate to improved quality of life for patients living with these non-healing foot ulcers."

NHS supply chain framework agreements, which can run for a period of up to 48 months, enable NHS trusts and healthcare organisations to procure goods and services. They provide a single route to market for suppliers, simplify procurement, and aim to deliver cost savings and efficiency while maintaining high clinical standards.

HE study supports cost savings and improved outcomes from NHS adoption of TWO2 Therapy

The authors of the study developed a comprehensive health economic model to estimate the cost effectiveness of $TWO_2^{(R)}$ therapy, using both the durable healing outcomes demonstrated in the pivotal TWO_2 Randomised Control

Trial (RCT) and UK healthcare cost norms. The model predicts that TWO₂[®] therapy would increase Quality Adjusted Life Years (QALYs) and significantly improve outcomes relative to standard care, while lowering costs by an estimated £5,038 per patient, or 16%, over the course of two years compared to the standard care cost of £31,275 per patient over the same period, meeting the QALY threshold commonly used by the National Institute for Health and Care Excellence (NICE) to determine whether new technology is considered "good value for money" and therefore suitable for funding within the NHS.⁵ AOTI has submitted its needs assessment application through NHS Innovation Service and looks forward to a future NICE technology appraisal (TA) guidance.

References

- 1. <u>https://doi.org/10.1016/j.jdiacomp.2025.109016</u>
- 2. <u>https://doi.org/10.1111/dme.13973</u>
- 3. https://lowdownnhs.info/social-care/spring-budget-2025-analysis-can-the-efficiency-drives-solve-health-crisis/
- 4. <u>https://jamanetwork.com/journals/jama/article-abstract/2806655</u>
- 5. https://www.nice.org.uk/news/blogs/should-nice-s-cost-effectiveness-thresholds-change-

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ABOUT AOTI, INC.

AOTI, INC. was founded in 2006 and is based in Oceanside, California, US and Galway, Ireland, providing innovative solutions to resolve severe and chronic wounds worldwide. Its products reduce healthcare costs and improve the quality of life for patients with these debilitating conditions. The Company's patented non-invasive Topical Wound Oxygen (TWO₂[®]) therapy has demonstrated in differentiating, robust, double-blinded randomised controlled trials (RCT) and real-world evidence (RWE) studies to more-durably reduce the recurrence of Diabetic Foot Ulcers (DFUs), resulting in an unprecedented 88 per cent reduction in hospitalisations and 71 per cent reduction in amputations over 12 months. TWO₂[®] therapy can be administered by the patient at home, improving access to care and enhancing treatment compliance. TWO₂[®] therapy has received regulatory clearance from the US (FDA), Europe (CE Mark), UK (MHRA), Health Canada, the Chinese National Medical Products Administration, Australia (TGA) and in Saudi Arabia. Also see <u>www.aotinc.net</u>

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