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AOTI, Inc.
11 November 2024

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

**CMS commences formal review for Topical Oxygen Therapy coverage**

AOTI, INC. (AIM: AOTI), a medical technology group focussed on the durable healing of wounds and prevention of amputations, is pleased to note that the Centers for Medicare and Medicaid Services (CMS), through its Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs), has scheduled a public Contractor Advisory Committee (CAC) meeting. The CAC meeting on 11 December 2024 will convene subject matter experts to consider revising the Oxygen and Oxygen Equipment Local Coverage Determination (LCD) to include language indicating that Topical Oxygen is reasonable and necessary for wound healing therapy.

The specialty focused CAC meeting is to discuss the scientific evidence underlying the requested LCD and to provide a formal mechanism for healthcare professionals to be informed of the evidence used in developing the LCD and promote communications between the DME MACs and the healthcare community. During the meeting, the CAC members will be asked to discuss the clinical literature related to the LCD reconsideration request and to score a series of key questions that will help guide CMS in drafting their proposed LCD revision. The DME MACs will then publish the proposed LCD and generally have up to 365 calendar days from the publication date to finalise the process.

**Dr. Mike Griffiths, Chief Executive Officer and President of AOTI, INC., commented:** *"Following the specialist led coverage reconsideration request made in mid-2023, we are delighted that CMS has decided to initiate their coverage review of topical oxygen therapy. Such coverage, if achieved, would provide significant additional momentum to accelerate our business trajectory above what we have outlined previously, and provide us with access to the c.65 million Americans covered by Medicare (the Government-funded healthcare insurance scheme for citizens 65 years of age and over).*

*"Our unique topical wound oxygen (*$TWO_2$®*) therapy has revolutionised chronic wound healing, by providing significant reductions in wound related reoccurrence, hospitalisations and amputations[1,2]. AOTI is proud to continue its efforts to expand the access of these benefits to all patients, predominately applied in their homes, thereby driving meaningful improvements in access-to-care for those who need it most."*

*1. Multinational, Multicenter, Randomized, Double-Blinded, Placebo-Controlled Trial to Evaluate the Efficacy of Cyclical Topical Wound Oxygen (TWO2) Therapy in the Treatment of Chronic Diabetic Foot Ulcers; The TWO2 Study. Robert G. Frykberg et al, Diabetics Care 2020; 43:616-624. https://doi.org/10.2337/dc19-0476*

*2. Reduced Hospitalizations and Amputations in Patients with Diabetic Foot Ulcers Treated with Cyclical Pressurized Topical Wound Oxygen Therapy: Real-World Outcomes; Jessica Izhakoff Yellin, et al; Advances in Wound Care 2022; http://doi.org/10.1089/wound.2021.0118*

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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 ($TWO_2$®) 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. $TWO_2$® therapy can be administered by the patient at home, improving access to care and enhancing treatment compliance. $TWO_2$® 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 www.aotinc.net



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