

Cost Effectiveness of Continuous Topical Oxygen Therapy for Unhealed Diabetic Foot Ulcers within the United States Veterans Health Administration

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Introduction

Annual prevalence of diabetic foot ulcers (DFUs) are approximately 26,000 within the US Veteran diabetic population and carry substantial risk of infection, amputation, and death.

~26,000 New DFUs Annually are Presented in the VHA

9.1M Veterans enrolled in VA health system¹

14.7% will have diabetes² = **1,337,700 Veterans**

13% prevalence of DFUs in Veterans with Diabetes³= **173,901 DFUs**

2% annual incidence of Veterans with DFUs⁴ = **26,754 new DFUs per year**

Continuous Topical Oxygen Therapy (cTOT)* has demonstrated improved healing rates in randomized controlled trials and meta-analyses.⁵⁻⁶ This model-based analysis evaluates the cost effectiveness and budget impact of adding cTOT to standard of care (SOC) for unhealed DFUs within the Veterans Health Administration (VHA).

Methods

The cost-effectiveness model uses a Markov structure to capture key resource use, cost, and quality-of-life impacts for a range of clinical outcomes following DFU treatment.⁷

The model used a VHA population of 9.1 million and a 5-year time horizon. Total DFUs of 173,901 were derived from 14.7% of the population having diabetes, and a DFU prevalence rate of 13%. Business Impact Models were created using population groupings of medium- and large-size VA hospitals.

Health states included:

- Unhealed DFU
- Minor amputation
- Healed DFU
- Major amputation
- Infection
- Death

Clinical inputs for healing rates were derived from published RCTs and meta-analyses of topical oxygen therapy in chronic DFUs (RR for complete healing: 1.53–1.94 vs. SOC). SOC was defined as offloading, debridement, moist wound management, infection control, and vascular assessment per International Working Group on the Diabetic Foot (IWGDF) guidelines.⁸ Costs were sourced from US federal pricing data. Outcomes were expressed as quality-adjusted life years (QALYs) and life years gained, with costs and outcomes discounted at 3% annually. Probabilistic sensitivity analysis (PSA) was performed across all model parameters.

Results

Over a 5-year horizon, adding cTOT to SOC saved an estimated \$7,444 per patient, yielding a dominant incremental cost-effectiveness ratio (ICER). Savings were driven primarily by reductions in infection episodes, amputations, and associated treatment costs. Over a five-year horizon, projected VHA-wide savings were estimated to be over \$1.2 billion. PSA showed a 94% probability that adding cTOT to SOC would be cost-saving compared to SOC alone.

Summary results	SOC Alone	NATROX® O ₂ + SOC	Savings
Total costs VHA population	\$8,414,198,588	\$7,119,701,576	\$1,294,497,012
Total costs per person	\$48,385	\$40,941	\$7,444

Discussion

This health economic analysis suggests that integrating cTOT into VHA DFU management is cost effective and potentially cost saving, with meaningful improvements in patient outcomes, including:

- Improved healing rates vs. SOC alone
- Lower amputation rates due to a reduction in infected ulcers
- Substantial cost savings at both patient and system levels

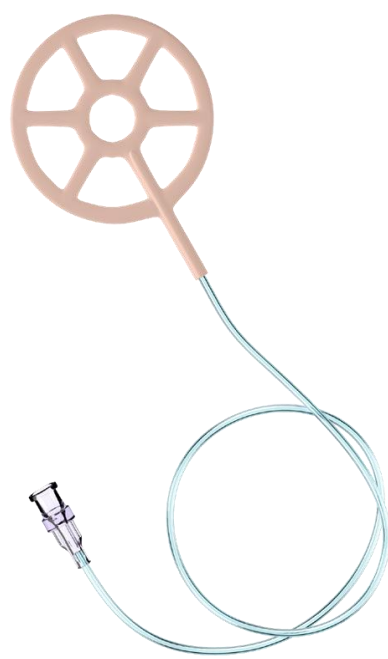
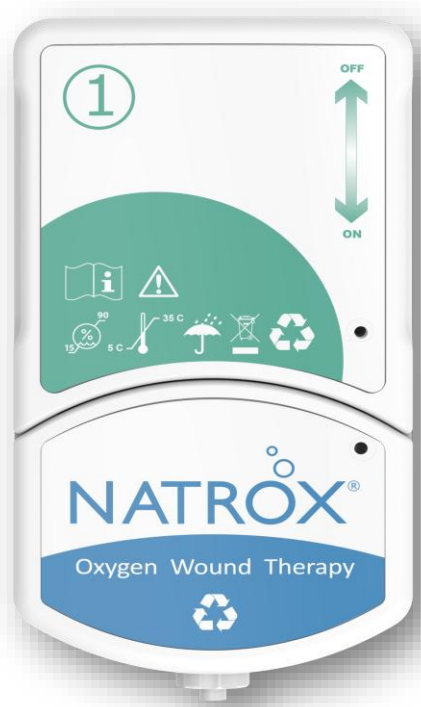
These findings support consideration of cTOT as an adjunctive therapy for unhealed DFUs within the VHA system.

References

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*NATROX® O₂ Continuous Topical Oxygen Therapy

Continuous Topical Oxygen (cTOT) Device*



NATROX® O₂ Oxygen Generator (OG)

- Simple-to-use, battery-operated device – delivers continuous oxygen to the wound bed at a flow rate of 11ml / hr.
- Rechargeable batteries – One is in use while the other is charging
- Wearable – Patients can remain mobile while receiving therapy
- Lightweight and discreet – Device can be carried in a pocket
- Silent – no alarms that would disturb sleep

NATROX® O₂ Oxygen Delivery System (ODS)

- Sterile, single-use wound interface oxygen delivery system
- Soft and pliable – Easily conforms to the wound's anatomical location
- Used as an adjunct to current standard of care wound management options on formulary, including compression and TCC
- “Wheel” like design optimizes the flow and diffusion of oxygen across the wound bed while allowing free passage of wound exudate into the secondary dressing
- Connects to the OG via a twist-and-lock attachment

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