

Topical Oxygen Wound Therapy (TOWT)

Topical Oxygen Wound Therapy (TOWT) is the controlled application of 100% oxygen at above normal atmospheric pressure directly to an open wound. An oxygen concentrator is connected to an FDA approved O2 boot, bag, or sacral device that is tightly sealed around the wound. High flow oxygen is pumped into the boot, bag, or sacral device. Devices are designed for onetime use and are disposable to reduce the risk of cross contamination.

TOWT is an existing benefit of the Medicaid program, and the Department will make a determination whether or not to continue coverage of this benefit.

Dossier Sources of Evidence Already Submitted:

The following evidence was recently submitted to the Department:

Systematic Reviews and Technology Assessments

1. Brem, H, et al. Cellular and molecular basis of wound healing in diabetes. *Journal of Clinical Investigations* 2007;1217:1219-1222.
2. Brimson, C, et al. The role of oxygen-associated therapies for the healing of chronic wounds, particularly in patients with diabetes. *J Eur Academy of Dermatology and Venereology* 2013;27:411-418.
3. ECRI Institute. ECRI Institute Hotline Response: Topical Oxygen Therapy for Chronic Wound Healing. Updated March 29, 2011.
4. Eisenbud, D. Oxygen in Wound Healing – Nutrient, Antibiotic, Signaling Molecule, and Therapeutic Agent. *Clin Plastic Surg* 2012;39:293–310.
5. Feldmeier, H, et al. UHMS Position Statement: Topical Oxygen for Chronic Wounds. *Undersea and Hyperbaric Medicine* 2005;32(3):157-168.
6. Fries, R, et al. Dermal excisional wound healing in pigs following treatment with topically applied pure oxygen. *Mutation Research* 2005;579:172-181.
7. Gordillo, G, et al. Revisiting the essential role of oxygen in wound healing. *Amer Journal of Surgery* 2003;186:259-263.
8. Gordillo, G, et al. Evidence-Based Recommendations for the Use of Topical Oxygen Therapy in the Treatment of Lower Extremity Wounds. *Intl Journal of Lower Extremity Wounds* 2009;8(2);105-111.
9. Orsted, H, et al. Evidence-based practice standards for the use of topical pressurized oxygen therapy. *Int Wound Journal* 2012;9:271–284.
10. Sen, C, et al. Oxygen, Oxidants and Antioxidants in Wound Healing. *Ann. N.Y. Acad. Sci* 2002;957:239–249.

11. Sen, C. Oxygen-Derived Hydrogen Peroxide as a Key Signal for Wound Healing. *Advances in Wound Care* 2010;2:123-127.

12. Sheikh, A, et al. . Effect of Hyperoxia on Vascular Endothelial Growth Factor Levels in a Wound Model. *Arch Surgery* 2000;135:1293-1297.

13. World Progress in Surgery. Editorial: Oxygen: At the Foundation of Wound Healing – Introduction. *World J Surg* 2004;28:291-293. Hunt T, et al. Guest Editors

Randomized Clinical Trials

14. Driver, V, et al. A prospective, randomized clinical study evaluating the effect of transdermal continuous oxygen therapy on biological processes and foot ulcer healing in persons with diabetes mellitus. *Ostomy Wound Management* 2013;59(11):19–26.

15. Heng, M. et al. Angiogenesis in necrotic ulcers treated with hyperbaric oxygen. *Ostomy Wound Management*. 2000;46(9):18-32.

16. Nie, K, et al. Clinical observation of basic fibroblast growth factor combined with topical oxygen therapy in enhancing burn wound healing. *Zhongguo Xiu Fu Chong Jian Wai Ke Za Zhi (Chinese Journal of Reparative and Reconstructive Surgery)*. 2010;24(6):643-646.

Cohort Studies

17. Blackman, E, et al. Topical wound oxygen therapy in the treatment of severe diabetic foot ulcers: a prospective controlled study. *Ostomy Wound Management*. 2010;56(6):24-31.

18. Gordillo, G, et al. Topical Oxygen Therapy Induces VEGF Expression and Improves Closure of Clinically Presented Chronic Wounds. *Clin Exp Pharmacol Physiol*. 2008 August; 35(8): 957–964.

19. Tawfick, W, et al. Does Topical Wound Oxygen (TWO2) Offer an Improved Outcome Over Conventional Compression Dressings (CCD) in the Management of Refractory Venous Ulcers (RVU)? A Parallel Observational Comparative Study. *Eur J Vasc Endovasc Surg* 2009; 38: 125-132.

20. Tawfick, W. et al. Technical and Clinical Outcome of Topical Wound Oxygen in Comparison to Conventional Compression Dressings in the Management of Refractory Nonhealing Venous Ulcers. *Vasc Endovascular Surg* 2013;47(1):30-37.

Case Series

21. Heng, MC, et al. Enhanced Healing and Cost-Effectiveness of Low-Pressure Oxygen Therapy in Healing Necrotic Wounds: A feasibility study of technology transfer. *Ostomy/Wound Management* 2000;46(3):52–62.

22. Japour, C. Combined wound therapy for recalcitrant diabetic pedal ulcers: a recent study indicates benefits from using topical hyperbaric oxygen therapy with Regranex Gel 0.01% - becaplermin. Article in *Podiatry Management* Nov-Dec 2003.

23. Kalliainen, L, et al. Topical oxygen as an adjunct to wound healing: a clinical case series. *Pathophysiology* 2003;9:81-87.

24. Woo, K, et al. Continuous Topical Oxygen for the Treatment of Chronic Wounds: A Pilot Study. *Adv Skin Wound Care* 2012;25:543-547.