

**Policy: MP224**

**Section: Medical Benefit Policy**

**Subject: Topical Oxygenation**

### Applicable Lines of Business

<b>Commercial</b>	<b>X</b>	<b>CHIP</b>	<b>X</b>
<b>Medicare</b>	<b>X</b>	<b>ACA</b>	<b>X</b>
<b>Medicaid</b>	<b>X</b>		

**I. Policy:** Topical Oxygenation

**II. Purpose/Objective:**

To provide a policy of coverage regarding Topical Oxygenation

**III. Responsibility:**

- A. Medical Directors
- B. Medical Management

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**Medicaid Business Segment**

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

**DESCRIPTION:**

Topical oxygenation, also referred to as topical hyperbaric oxygenation, is the use of 100% oxygen applied at just above atmospheric pressure to moist open wounds. The theory behind this therapy is that the increase in oxygen at the surface of the wound speeds healing. Unlike hyperbaric oxygen therapy (addressed in MP47) which involves whole-body pressurization and inhalation of 100% oxygen at a minimum of 1.4 (usually 1.4-2.5) atmospheres, topical oxygenation is delivered via a specially constructed chamber that fits around a limb or by using disposable polyethylene bags that surrounds the wound area, and oxygen is delivered under pressure from a source that may be a conventional oxygen tank. Examples of topical Hyperbaric Oxygen Therapy (HBOT) devices include but are not limited to TOPOX portable hyperbaric oxygen extremity and sacral chambers, Oxyboot and Oxyhealer from GWR Medical, L.L.P.

**EXCLUSIONS:**

The current body of evidence in the peer-reviewed, published medical literature supporting the use of topical oxygenation for any indication is insufficient to allow adequate conclusions regarding efficacy. The Plan does **NOT** provide coverage for topical oxygenation because it is considered **experimental, investigational or unproven**.

For information on full body hyperbaric oxygen therapy please refer to **MP 47** Hyperbaric Oxygen Therapy.

**Medicaid Business Segment:**

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

**Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.**

**CODING ASSOCIATED WITH:** Topical Oxygenation

*The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements*

A4575 Topical hyperbaric oxygen chamber, disposable

E0446 Topical oxygen delivery system, not otherwise specified, includes all supplies.

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

**LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

**REFERENCES:**

Feldmeier JJ, Hopf HW, Warriner RA 3rd, UHMS position statement: Topical oxygen for chronic wounds. Undersea Hyperb Med. 2005;32(3):157-168

Undersea and Hyperbaric Medicine Society. Indications for Hyperbaric Oxygen Therapy.  
<http://www.uhms.org/Default.aspx?tabid=270>

ECRI Institute, HTAIS Custom Hotline Service. Topical Oxygen therapy for Chronic Wound Healing.

Heng MCY. Topical hyperbaric therapy for problem skin wounds. J Dermatol Surg Oncol 1993;19:784-93

Leslie CA, Sapico FL, Ginunas VJ, Adkins RH. Randomized controlled trial of topical hyperbaric oxygen for treatment of diabetic foot ulcers. Diabetes Care 1988;11:111-15

Kalliainen LK, Gordillo GM, Schlanger R. Topical oxygen as an adjunct to wound healing: a clinical case series. *Pathophysiology* 2003;9:81-87

Landau Z. Topical hyperbaric oxygen and low energy laser for the treatment of diabetic foot ulcers resistant to conventional treatment. *Yale J Biol Med* 2001; 74(2):95-100.

Edsburg LE. Topical hyperbaric oxygen and electrical stimulation: exploring potential synergy. *Ostomy Wound Manage.* 2002;48(11):42-50

Gordillo GM, Roy S, Khanna S, Schlanger R, Khandelwal S, Phillips G, et al. Topical oxygen therapy induces vascular endothelial growth factor expression and improves closure of clinically presented chronic wounds. *Clin Exp Pharmacol Physiol.* 2008;35(8):957-964.

Upton AV. Topical hyperbaric oxygenation in the treatment of recalcitrant open wounds. A clinical report. *Physical Therapy* 1986;66(9):1408-1412.

Stone JA, Cianci P. The adjunctive role of hyperbaric oxygen therapy in the treatment of lower extremity wounds in patients with diabetes. *Diabetes Spectrum* 1997;10(2):118-123.

Piantadosi CA. Topical oxygen is not hyperbaric oxygen (HBO2). *UHM* 2003;30(4):267-269.

Heng MC, Harker J, Csathy G, Marshall C et al. Angiogenesis in necrotic ulcers treated with hyperbaric oxygen. *Ostomy Wound Management* 2000;46(9):18-28.

Centers for Medicare and Medicaid Services (CMS). *National Coverage Determination (NCD)*. 20.29: Hyperbaric oxygen therapy. [CMS Web site]. 06/19/06. Available at: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=12&ncdver=3&DocID=20.29&bc=gAAAAAgAAAA&>. Accessed October 22, 2016.

Novitas Solutions Inc. Medicare Local Coverage Determination (LCD). L35021 Hyperbaric Oxygen (HBO) Therapy

Rao C, Xiao L, Liu H, et al. Effects of topical oxygen therapy on ischemic wound healing. *J Phys Ther Sci.* 2016;28(1):118-123.

Sayadi LR, Banyard DA, Ziegler ME, et al. Topical oxygen therapy & micro/nanobubbles: a new modality for tissue oxygen delivery. *Int Wound J.* 2018;15(3):363-374.

Kaufman H, Gurevich M, Tamir E, Keren E, Alexander L, Hayes P. Topical oxygen therapy stimulates healing in difficult, chronic wounds: a tertiary centre experience. *J Wound Care.* 2018;27(7):426-433.

Thanigaimani S, Singh T, Golledge J. Topical oxygen therapy for diabetes-related foot ulcers: A systematic review and meta-analysis. *Diabet Med.* 2021;38(8):e14585.

Connaghan F, Avsar P, et al. Impact of topical oxygen therapy on diabetic foot ulcer healing rates: a systematic review. *J Wound Care.* 2021 Oct 2;30(10):823-829

Song Z, Guo X, Zhang X. Effects of topical oxygen therapy on chronic traumatic wounds and its impact on granulation tissue. *Am J Transl Res.* 2021;13(6):7294-7299

Serena TE, Bullock NM, Cole W, et al. Topical oxygen therapy in the treatment of diabetic foot ulcers: A multicentre, open, randomised controlled clinical trial. *J Wound Care.* 2021;30(Sup5):S7-S14.

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 12/03/08

**Revised:**

**Reviewed:** 1/10, 12/10 (coding), 12/11, 12/12, 12/13, 12/14, 12/15, 12/16, 11/17, 11/18, 11/19, 11/20, 11/21, 11/22, 11/23

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.