

Topical Oxygen Therapy

Policy Number: **M20150417024**
Effective Date: **6/1/2015**
Sponsoring Department: **Health Care Services**
Impacted Department(s): **Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐ Confidential ☐ Restricted ☒ Public

Applies to (Line of Business):

- ☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒ MediSource; ☒ MediSource Connect; ☒ Child Health Plus ☒ Essential Plan
☒ Medicare, if yes, which plan(s): ☒ MAPD; ☐ PDP; ☒ ISNP; ☒ CSNP
☒ Commercial, if yes, which type: ☒ Large Group; ☒ Small Group; ☒ Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

Applicable to Vendors? Yes ☐ No ☒

Purpose and Applicability:

To set forth the medically necessary criteria for **topical oxygen therapy**.

Policy:

Background:

Topical oxygen therapy provides localized oxygen delivery directly to the wound bed and periwound surfaces. This option may be more acceptable to patients who are not candidates for HBOT or who find the frequency of HBOT cumbersome. To date there are no peer-reviewed studies directly comparing the outcomes of HBOT with topical oxygen therapy or that establish the efficacy of topical oxygen through well-controlled clinical trials.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined below.

Commercial, Self-Funded and Medicare Advantage:

The efficacy of topical oxygen application for wound care has not been established with scientific clinical evidence so it is considered not medically necessary.

MediSource, MediSource Connect, Child Health Plus and Essential Plan: cover Topical Oxygen Wound Therapy (TOWT) utilizing the criteria below.

TOWT should be attempted first in a hospital or another health care facility prior to discharge to the home setting. In these continuing cases, documentation should reflect member compliance and pain management during application of TOWT. If TOWT has not been attempted, DMEPOS providers must obtain an initial electronic prior authorization of two weeks (8 days or units) only. Prior approval may then be requested for an extension of the treatment.

Documentation of previous treatment regimens and how the member meets the coverage criteria below must be maintained in the member's medical record and available upon request. This documentation must include dressing types and frequency of change, changes in wound conditions (including precise length, width and surface area measurements), quantity of exudates, presence of granulation and necrotic tissue, concurrent measures being addressed relevant to wound therapy (debridement, nutritional concerns, support surfaces in use, positioning, incontinence control, etc.) and training received by the member/family in the application of the occlusive dressing to the wound site and proper hook up of the oxygen to the dressing set.

Upon completion of treatment, documentation regarding the outcome of treatment with TOWT must be submitted to the prior approval office.

Clinical Indications:

Per New York State Clinical Criteria, initial TOWT is covered for State product members, for **ALL** of the following:

- A complete wound therapy program has been attempted prior to TOWT, including **ALL** of the following:

- Documentation in the member's medical record of evaluation, care, compliance and wound measurements by the treating physician
- Application of dressings to maintain a moist wound environment
- Debridement of necrotic tissue or no necrotic tissue is present
- Evaluation of and provisions for adequate nutritional status
- **1 or more** of the following clinical indications:
 - Stage IV pressure ulcers and **ALL** of the following:
 - Documentation that the member has been turned and positioned
 - Documentation that the member has used a support surface for pressure ulcers on the posterior trunk or pelvis, or that the ulcer is not on those body areas
 - Documentation that the member's moisture and incontinence have been appropriately managed
 - Neuropathic (for example, diabetic) ulcers and **ALL** of the following:
 - Documentation that the member has been on a comprehensive diabetic management program
 - Documentation that reduction in pressure on a foot ulcer has been accomplished
 - Venous insufficiency ulcers and **ALL** of the following:
 - Compression bandages and/or garments have been consistently applied
 - Leg elevation and ambulation have been encouraged
 - Non-healing surgically created or traumatic wounds with documentation of medical necessity for accelerated formation of granulated tissue not achieved by other topical wound treatments
 - A chronic (present for 30 days or more) ulcer of mixed etiology
- **1 or more** of the following situations:
 - Documentation that this is an initial request
 - Documentation that this is a request for an extension of treatment and **ALL** of the following:
 - That the member meets the initial coverage criteria
 - Documentation of the status of wound healing
 - Documentation of weekly quantitative measurements of wound characteristics, wound length, width and depth (surface area) and amount of wound exudate (drainage)
 - Documentation of member compliance with the treatment plan

TOWT is considered investigational, not medically necessary, and medically contraindicated for all other indications. TOWT is **NOT COVERED** for **ANY** of the following:

- For Commercial, Self-Funded and Medicare Advantage members, **considered investigational**
- The presence in the wound of necrotic tissue with eschar, if debridement is not attempted
- Untreated osteomyelitis within the vicinity of the wound

- Cancer present in wound
- The presence of a fistula to an organ or body cavity within the vicinity of the wound
- Stage I, II or III pressure ulcers

Pre-Authorization Required? Yes ☒ No ☐

Pre-authorization is required for this service.

Definitions

Topical oxygen wound therapy (TOWT) involves the application of gaseous oxygen to a cutaneous wound. Oxygen is pumped into the bag or plastic sheet as the elevated pressure is believed to facilitate diffusion of oxygen into the wound. Treatment protocols may vary however wounds are typically exposed to gaseous oxygen for 4 treatment sessions per week for a total of 14-16 sessions over 4 weeks.

The **staging of pressure ulcers** used in the above policy is as follows:

- **Stage I:** nonblanchable erythema of intact light toned skin or darker or violet hue in darkly pigmented skin.
- **Stage II:** partial thickness skin loss involving epidermis and/or dermis.
- **Stage III:** full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia.
- **Stage IV:** full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures.

Wound healing is defined as improvement occurring in either the surface area or depth of the wound. Lack of improvement of a wound is defined as a lack of progress in these quantitative measurements.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

Berlowitz, D. Clinical staging and management of pressure-induced skin and soft tissue injury. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on March 8, 2024).

Canada's Drug and Health Technology Agency (CADTH) [web site]. CADTH Rapid Response Report: Summary With Critical Appraisal: Continuously Diffused Oxygen Therapy for Wound Healing: A Review of the Clinical Effectiveness, Cost-Effectiveness, and Guidelines. July 16, 2020. Available at:

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Accessed February 28, 2025.

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

Hayes, Inc. Health Technology Assessment Topical Oxygen Therapy for Chronic Wound Healing. Lansdale, PA: November 2017.

Ubbink DT, Westerbos SJ, Evans D, et al. Topical negative pressure for treating chronic wounds. Cochrane Database Syst Rev. 2008 Jul 16;(3):CD001898.

Ubbink DT, Westerbos SJ, Nelson EA, et al. A systematic review of topical negative pressure therapy for acute and chronic wounds. Br J Surg. 2008 Jun;95(6):685-92.

Undersea and Hyperbaric Medical Society [web site]. UHMS Position Statement: Topical Oxygen for Chronic Wounds. Date revised/updated: May 23, 2018. Available at:

https://www.uhms.org/images/Position-Statements/UHMS_Position_Statement_on_Topical_Oxygen_2018_May_Final.pdf

Accessed February 28, 2025.

Regulatory References

New York State Department of Health [web site]. New York State Medicaid Program Durable Medical Equipment, Orthotics, Prosthetics, and Supplies Procedure Codes and Coverage Guidelines. Version Durable Medical Equipment, Orthotics, Prosthetics and Supplies Procedure Codes and Coverage Guidelines Version 2025 (5/1/2025). Available at:

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New York State Department of Health; Division of Managed Care Covquest, February 6, 2002, rev. December 6, 2010, MA – 00019. Topical Oxygen Wound Therapy.

New York State Medicaid Topical Oxygen Wound Therapy Guidelines. March 2008. Available at:

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Accessed February 28, 2025.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No ☐

Revision Date	Owner	Notes
8/1/2025	Health Care Services	Revised- Formatting only
5/1/2025	Health Care Services	Reviewed

5/1/2024	Health Care Services	Revised
1/1/2024	Health Care Services	Revised
5/1/2023	Health Care Services	Revised
5/1/2022	Health Care Services	Reviewed
5/1/2021	Health Care Services	Reviewed
5/1/2020	Health Care Services	Reviewed
6/1/2019	Medical Management	Revised
6/1/2018	Medical Management	Revised
6/1/2017	Medical Management	Revised
7/1/2016	Medical Management	Revised