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:

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:
Topical Oxygen Wound Therapy (TOWT) is the controlled application of 100% oxygen directly to an open moist wound at slightly higher than atmospheric pressure. An oxygen concentrator is connected to an O2 boot and /or sacral device that is utilized only one time and disposed of to reduce the risk of cross-contamination.

A. New York State Clinical Criteria:

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: 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.

TOWT is covered when criteria 1 and any of criteria 2-6 are met:

1. A complete wound therapy program has been attempted prior to TOWT, including:
    i. Documentation in the member's medical record of evaluation, care, compliance and wound measurements by the treating physician; and
    ii. Application of dressings to maintain a moist wound environment; and
    iii. Debridement of necrotic tissue if present; and
    iv. Evaluation of and provisions for adequate nutritional status; and

2. Stage IV pressure ulcers:
    i. Member has been turned and positioned, and
    ii. The member has used a support surface for pressure ulcers on the posterior trunk or pelvis (not required if ulcer is not on those body areas),
    iii. The member's moisture and incontinence have been appropriately managed; or

3. Neuropathic (for example, diabetic) ulcers:
    i. The member has been on a comprehensive diabetic management program, and
    ii. Reduction in pressure on a foot ulcer has been accomplished, or

4. Venous insufficiency ulcers:
    i. Compression bandages and/or garments have been consistently applied, and

ii. Leg elevation and ambulation have been encouraged, or

5. For non-healing surgically created or traumatic wounds, documentation of medically necessity for accelerated formation of granulated tissue not achieved by other topical wound treatments; or

6. A chronic (present for 30 days or more) ulcer of mixed etiology.

7. 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.

8. Documentation of previous treatment regimens and how the member meets the coverage criteria above 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.

9. When an extension of treatment is requested, the following documentation must be submitted: how the member meets the coverage criteria, status of wound healing, weekly quantitative measurements of wound characteristics, wound length, width and depth (surface area) and amount of wound exudate (drainage) and member compliance with the treatment plan. If detailed documentation is insufficient or if any measurable degree of wound healing has failed to occur, prior approval beyond the initial approved period of service will not be granted.

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

B. Non-covered Indications:

TOWT is considered investigational, not medically necessary, medically contraindicated and not covered for all other indications, including but not limited to, the following:

1. The presence in the wound of necrotic tissue with eschar, if debridement is not attempted;
2. Untreated osteomyelitis within the vicinity of the wound;
3. Cancer present in wound;
4. The presence of a fistula to an organ or body cavity within the vicinity of the wound;
5. Stage I, II or III pressure ulcers.

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 above.

Pre-Authorization Required? Yes ☒ No☐

Pre-authorization is required for this service.

Definitions

Topical oxygen therapy 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.

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: https://www.cadth.ca/sites/default/files/rr/2020/RC1292%20TWO2%20Final.pdf Accessed March 8, 2024.

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.

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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 2023 (4/1/2023). Available at: https://www.emedny.org/providermanuals/dme/pdfs/dme_procedure_codes.pdf Accessed March 8, 2024.

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: https://www.emedny.org/providermanuals/DME/PDFS/2008-4_New%20York%20State%20Medicaid%20Topical%20Oxygen%20Wound%20Therapy%20Guidelines.pdf Accessed March 8, 2024.

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
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
