MetroPlus Health

Policy and Procedure

Title: Topical Oxygen Therapy	**Division: Medical Management** **Department: Utilization Management**
Approval Date: 11/3/17	**LOB: Medicaid, HIV SNP, HARP, UltraCare, Medicare IB Dual**
Effective Date: 11/3/17	**Policy Number: UM-MP222**
Review Date: 9/23/24	**Cross Reference Number:**
Retired Date:	**Page 1 of 7**

1. POLICY DESCRIPTION:

This policy describes the conditions under which MetroPlus will cover topical oxygen therapy. For the UltraCare and Medicare IB Dual lines of business, topical oxygen therapy is covered through Medicaid.

2. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

3. DEFINITIONS:

Durable Medical Equipment: (18 NYCRR 505.5) Devices and equipment, other than prosthetic or orthotic appliances, which have been ordered by a practitioner in the treatment of a specific medical conditions and which have all of the following characteristics:

- **a.** Can withstand repeated use for a protracted period of time
- **b.** Are primarily and customarily used for medical purposes
- **c.** Are generally not useful in the absence of an illness or injury
- **d.** Are not usually fitted, designed or fashioned for a particular individual's use
- **e.** Where equipment is intended for use by only one beneficiary, it may be either custom-made or customized.

Hyperbaric oxygen therapy: A patient is completely enclosed inside some type of chamber, the ambient pressure is raised well above sea level pressure (760 torr), usually to at least twice sea level pressure (1520 torr). The concentration of oxygen in the surrounding air is raised well above standard atmospheric (21%). Hyperbaric oxygen therapy is not the subject of this policy. We include the definition to avoid confusion

Topical oxygen therapy (TOT), also known as topical oxygen wound therapy (TOWT) or topical hyperbaric oxygen therapy: The controlled application of 100% oxygen directly to an open moist wound at slightly higher than atmospheric pressure. An oxygen concentrator is connected to a FDA approved O2 boot and/or O2 sacral device that are for onetime use and disposable, therefore reducing the risk of cross contamination. The term “topical hyperbaric” is misleading; since increasing the pressure over the wound even slightly (e.g. from 760 torr to 770 torr) wound significantly obstruct venous blood flow and worsen wound healing. These devices do not provide appreciable “hyperbaric” (“high pressure”) therapy.

Pressure Ulcers: Skin lesions caused by prolonged local pressure to an area of skin so that the circulation in compromised and the skin necroses (dies). By NYS guidelines, pressure ulcers are divided into stages:

a. **Stage I**: non blanchable erythema of intact light toned skin or darker or (violet hue) in darkly pigmented skin**.**
b. **Stage II**: partial thickness skin loss involving epidermis and/or dermis.
c. **Stage III**: full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia.
d. **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 surface area or depth of the wound. Lack of improvement of a wound is defined as a lack of progress in these quantitative measurements.

Treating Physician: For the purposes of this policy, a licensed medical doctor (MD) or doctor of osteopathy (DO) with expertise in wound healing.

Relevant conditions: For the purposes of this policy, comorbidities which could affect wound healing, including nutritional, vascular, metabolic, compliance, substance use and social conditions

4. POLICY:

MetroPlus follows New York State Medicaid guidelines for our Medicaid patients. New York State Medicaid coverage for TOT undergoes frequent discussion and guideline revision. The policy addresses MetroPlus covering the current NYS Medicaid policy (reference 1). MetroPlus policy may change in the future to reflect changes in New York State Medicaid policy.

MetroPlus will cover TOT for Medicaid members when criteria 1 and any of criteria 2-6 are met:

1. A complete wound therapy program as applicable, depending on the type of wound, has been attempted prior to the application of TOWT, including:
    a. Documentation in the member's medical record of evaluation, care, compliance, and wound measurements by the treating physician, and
    b. Application of dressings to maintain a moist wound environment, and
    c. Debridement of necrotic tissue if present, and

   d. Evaluation of and provision for adequate nutritional status, and
   e. Must have documentation of failure of comprehensive wound care as appointed for the specific wound type. Failure is defined as worsening of the wound in the previous 2 weeks despite comprehensive care or a failure of the wound to prove any signs of healing after 30 days of comprehensive care.
2. Stage IV pressure ulcers:
   a. The member has been appropriately turned and positioned, and
   b. The member has used a support surface for pressure ulcers on the posterior trunk or pelvis (not required if the ulcer is not on the trunk or pelvis), and
   c. The member's moisture and incontinence have been appropriately managed, or
3. Neuropathic (for example, diabetic) ulcers:
   a. The member has been on a comprehensive diabetic management program, and
   b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities, or
4. Venous insufficiency ulcers:
   a. Compression bandages and/or garments have been consistently applied, and
   b. Leg elevation and ambulation have been encouraged, or
5. For non-healing surgically created or traumatic wounds, documentation of medical necessity for accelerated formation of granulation tissue that cannot be achieved by other topical wound treatments, or
6. A chronic (being present for at least 30 days) ulcer of mixed etiology.

An initial prior authorization will be granted (for A4575) for a maximum of 16 days in a 28-day period, as treatment is 4 days on, 3 days off. New authorization is required after the initial 4 weeks.

When an extension of treatment is requested, the following documentation must be submitted:

1. how the patient meets the coverage criteria;
2. status of wound healing;
3. weekly quantitative measurements of wound characteristics, wound length, width, and depth (surface area) and amount of wound exudate (drainage);
4. patient 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.

TOWT is considered not medically necessary 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 the 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.

Notes:

1. 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 patient compliance and pain management during application of TOWT. If TOWT has not been attempted, 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.
2. The procedure codes for billing TOWT are *A4575 Topical oxygen chamber, disposable* and *E1390 Oxygen concentrator, single delivery port, capable of delivering 85% or greater oxygen concentration at the prescribed flow rate*.
3. Payment for E1390 includes all necessary equipment, delivery, maintenance and repair costs, parts, supplies and services for equipment set-up, maintenance, and replacement of worn essential accessories and parts.
4. Payment for A4575 includes the dressing set and canister set used in conjunction with E1390 and contains all necessary components, including but not limited to an occlusive dressing which creates a seal around the wound site for maintaining the desired concentration of oxygen at the wound. Payment for E1390 and A4575 is considered payment in full for TOWT.
5. Documentation of previous treatment regimens and how the patient meets the coverage criteria above must be maintained in the patient'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 patient/family

in the application of the occlusive dressing to the wound site and proper hook up of the oxygen to the dressing set.

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

5. LIMITATIONS/ EXCLUSIONS:

1. Medicaid is the only plan for which TOT may be covered.
2. Conditions which cause or exacerbate the wound must be maximally treated , such as nutritional deficiency, congestive heart failure, venous stasis with or without thrombosis, and nicotine/carbon monoxide poisoning.
3. Therapy will be continued only if there is measurable, verifiable evidence of wound healing over time.

6. APPLICABLE PROCEDURE CODES:

CPT	Description
A4575	Topical oxygen chamber, disposable and
E1390	Oxygen concentrator, single delivery port, capable of delivering 85% or greater oxygen concentration at the prescribed flow rate

7. REFERENCES:

1) New York State Medicaid, Durable Medical Equipment, Prosthetics, and Orthotics, DME Procedure Codes & Coverage Guidelines https://www.emedny.org/ProviderManuals/DME/PDFS/DME_Procedure_Codes.pdf

2) UpToDate: Overview of treatment of chronic wounds https://www.uptodate.com/contents/overview-of-treatment-of-chronic-wounds?search=topical%20oxygebn%20wound%20therapy&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

3) Frans J Cronjé. Oxygen therapy and wound healing – topical oxygen is not hyperbaric oxygen therapy. Forum, South African Medical Journal. November 2005, Vol. 95, No. 11 p 840

4) PAOLA G. RODRIGUEZ, BS, FRANCES N. FELIX, BS,DAVID T. WOODLEY, MD, AND ELISABETH K. SHIM, The Role of Oxygen in Wound Healing: A Review of the Literature. Dermatol Surg 2008;34:1159–1169 _

5) Jürg Hafner, Iris Schaad, Ernst Schneider,Burkhardt Seifert, Günter Burg, MD,a and Paolo Claudio Cassina, Leg ulcers in peripheral arterial disease (arterial leg

ulcers): Impaired wound healing above the threshold of chronic critical limb ischemia (J Am Acad Dermatol 2000;43:1001-8.)

6) Gayle M. Gordillo, M.D., Chandan K. Sen, Ph.D.* Revisiting the essential role of oxygen in wound healing The American Journal of Surgery 186 (2003) 259–263
7) S. Schreml, R.M. Szeimies, L. Prantl,* S. Karrer, M. Landthaler and P. Babilas. Oxygen in acute and chronic wound healing British Journal of Dermatology 2010 163, pp257–268
8) Hunt TK. Vitamin A and Wound Healing. Surgical Forum 21:81-82 1970
9) CHANDAN K. SEN, SAVITA KHANNA, GAYLE GORDILLO, DEBASIS BAGCHI, MANASHI BAGCHI, AND SASHWATI ROY. Oxygen, Oxidants, and Antioxidants in Wound Healing An Emerging Paradigm Ann. N.Y. Acad. Sci. 957: 239–249 (2002).
10) Gayle M. Gordillo, MD, and Chandan K. Sen, Evidence-Based Recommendations for the Use of Topical Oxygen Therapy in the Treatment of Lower Extremity Wounds. The International Journal of Lower Extremity Wounds Volume 8 Number 2 June 2009 105-111

8.

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Approved:	Date:	Approved:	Date:
David Ackman Digitally signed by David Ackman Date: 2024.09.30 14:22:23 -04'00'		Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2024.10.15 15:09:32 -04'00'	
David Ackman, MD **VP of Medical Director**		**Sanjiv Shah, MD** **Chief Medical Officer**	

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Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and or paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization