

NEW YORK STATE MEDICAID
TOPICAL OXYGEN WOUND THERAPY
GUIDELINES

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Introduction

The purpose of these guidelines is to provide detailed coverage criteria for **Topical Oxygen Wound Therapy (TOWT)** to all stakeholders so that medically necessary equipment is provided to Medicaid beneficiaries in a timely manner. Written comments and feedback on this document may be directed to:

Office of Health Insurance Programs
 Division of Utilization Management and Provider Relations
 150 Broadway, Suite 6E, Albany, NY 12204
 (Attn: DME/TOWT Guidelines)

I. General Definitions

1. 18 NYCRR 505.5, states that durable medical equipment (DME) are devices and equipment, other than prosthetic or orthotic appliances, which have been ordered by a practitioner in the treatment of a specific medical condition and which have all the following characteristics:
 - Can withstand repeated use for a protracted period of time;
 - Are primarily and customarily used for medical purposes;
 - Are generally not useful in the absence of an illness or injury;
 - Are not usually fitted, designed or fashioned for a particular individual's use;
 - Where equipment is intended for use by only one beneficiary, it may be either custom-made or customized.
2. **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 a FDA approved O2 boot and/or O2 sacral device that are for one-time use and disposable, therefore reducing the risk of cross contamination. Studies indicate that concentration of oxygen at the wound site increases the local cellular oxygen tension, which in turn promotes wound healing.
3. The staging of **pressure ulcers** used in this 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.
4. **Wound healing** is 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.

II. Criteria for Coverage

TOWT (A4575 with E1390) is covered 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 application of TOWT, including:
 - a. Documentation in the patient'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
2. Stage IV pressure ulcers:
 - a. The patient has been appropriately turned and positioned, and
 - b. The patient 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 patient's moisture and incontinence have been appropriately managed, or
3. Neuropathic (for example, diabetic) ulcers:
 - a. The patient 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 granulated tissue as a result of which cannot be achieved by other topical wound treatments, or
6. A chronic (being present for at least 30 days) ulcer of mixed etiology.

III. 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:

- 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 the 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.

IV. General Requirements

Department regulations and policies regarding ordering and provision of DME are available at: <http://www.nyhealth.gov/nysdoh/phforum/nycrr18.htm>, and in the DME Provider Manual, at www.emedny.org/ProviderManuals/DME/index.html. Specifically:

1. 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*.
2. 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. 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.
3. An initial electronic prior authorization (DVS) 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. The provider should request authorization once for the number of days (units) based on the written order. Prior approval is required for treatment exceeding 4 weeks. E1390 is not prior authorized and is billed monthly.
4. 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.
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. When an extension of treatment is requested, the following documentation must be submitted: how the patient 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 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.

7. Upon completion of treatment, documentation regarding the outcome of treatment with TOWT must be submitted to the prior approval office.
8. All services must be supported by the original, signed written order specific to the item being requested from a qualified licensed prescriber (DME Manual, Policy Section).
9. All providers are responsible for assuring that adequate and less costly alternatives for services have been explored and, where appropriate and cost effective, are provided (18NYCRR 513).
10. It is an unacceptable practice to order or furnish inappropriate, improper, unnecessary or excessive services. Providers engaging in unacceptable practices are subject to liability for overpayments or penalties and administrative action that could affect their continued participation in the Medicaid Program (18 NYCRR 515.2).
11. The financial liability of the ordering practitioner as well as the provider of any durable medical equipment, medical/surgical supplies, orthotic and prosthetic appliances or devices or orthopedic footwear determined on audit not to be medically necessary is set forth in 18NYCRR 518.