UM-CDG-092 Topical Oxygen Therapy	Approved By: Director, Health Services	Effective Date: 10/20/2025

This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address topical oxygen therapy (TOT). OT administered to the open wound in small limb-encasing devices is not typically hyperbaric oxygen (HBO) therapy, and its efficacy has not been established due to the lack of controlled clinical trials. In addition, in vitro evidence suggests that TOT does not increase tissue oxygen tension beyond the superficial dermis. Examples of TOT devices are TOPOX portable HBO extremity and sacral chambers (Jersey City, NJ), Oxyboot® and Oxyhealer® from GWR Medical, L.L.P. (Chadds Ford, PA).

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

None

POLICY

SECUR Health Plan considers TOT to be a method whereby a local supply of oxygen is applied to a wound (Dissemond, Kroger, Storck, Risse, & Engels, 2015). It is delivered by 1 of 2 techniques (Woo, Coutts, & Sibbbald, 2012). In the first, oxygen may be delivered intermittently through an airtight chamber or soft sided 'bag' that is sealed around a wound present on the trunk or limb of the body. The bag or chamber is filled with 100% oxygen at high flow rates (e.g., 10L /min) from an external source to pressures slightly above atmospheric (e.g., 1.004 – 1.013 atm abs) and is delivered to the patient on an intermittent dosing schedule (Feldmeier et al., 2005; Howard et al., 2013). In the past, this type of oxygen delivery was known by some as topical HBO therapy, a term that is less commonly used today due to the low pressures delivered (Brimson & Nigam, 2013). Topical oxygen can also be delivered to a wound when applied continuously by a tube supplying pure oxygen at a normobaric pressure and low flow rate (3-12 ml/hour) under an occlusive dressing (Howard et al., 2013). These devices have been variously termed transcutaneous oxygen, transdermal continuous oxygen therapy (TCOT), low flow oxygen, topical continuous oxygen therapy, continuous topical oxygen and CDO (Dissemond, Kroger, Storck, Risse, & Engels, 2015; Howard et al., 2013; Lowell, Nicklas, Weily, Johnson, & Lyons, 2009; Orsted et al., 2012; Woo et al., 2012).

Neither intermittent nor continuous provision of topical oxygen is dependent on the systemic circulation reaching

the wound, as is the case with HBO. However, because these systems directly apply oxygen to the wound site, it is thought by some that the oxygen can penetrate directly into the injured area, and therefore, improve healing of cutaneous lesions (Brimson & Nigam, 2013; Howard et al., 2013; Orsted et al., 2012; Woo et al., 2012). Typically, intermittent TOT treatments would be administered 4 to 5 days a week for approximately 90 minutes per session (Howard et al., 2013), though there can be other variations of dosaging noted in the clinical protocols. HBO must be provided in medically supervised environments; however, intermittent TOT may be provided in the home setting by a well-trained patient or caregiver. Though infrequent, side effects of HBO can be significant and include the possibility of pneumothorax, ear and sinus barotrauma, pulmonary edema, worsening of congestive heart failure, seizures and retinal damage (Howard et al., 2013). There are also significant concerns among some in the wound care community regarding TOT administered intermittently. For example, some believe that intermittent TOT may impede arterial or capillary circulation, inhibit angiogenesis, and decrease collagen synthesis and fibroblast proliferation; all circumstances which would delay or inhibit healing of a wound (Mutluoglu, Cakkalkurt, Uzun, & Aktas, 2015). TOT may not be appropriate for wounds covered in eschar or those that are deep and penetrating. Moreover, when used on open, exposed wound surfaces, TOT may cause desiccation of the area (Howard et al., 2013). TOT has been proposed in the treatment of skin ulcerations resulting from diabetes, venous stasis, post-surgical infections, gangrenous lesions, pressure ulcers/decubitus ulcers, infected residual limbs, skin grafts, burns and frostbite.

The goal of topical continuous oxygen therapy is to provide an uninterrupted and continuous supply of oxygen to a moist wound. The dressing is designed such that the oxygen is supplied in a manner that most closely approximates the normal diffusion of oxygen in moist tissues, yet a rate sufficient to fuel the increased oxygen demands required in healing tissues. With this therapy, the dressing helps provide an environment for optimal wound healing while managing wound exudate levels, protecting against wound dehydration and protecting against external contamination. Contraindications to this wound therapy includes wounds with inadequate perfusion to support healing; ulcers due to acute thrombophlebitis; ulcers due to Raynaud's disease; necrotic wounds covered with eschar or slough; wounds with fistulae or deep sinus tracts with unknown depth.

The following are Federal Drug Administration (FDA)-approved TOT devices:

- EPIFLO® TCOT (Ogenix®) consists of a small, silent, disposable, oxygen concentrator and a long sterile cannula (tube). It is used with any fully occlusive sterile wound dressing to continuously blanket the wound with near 100% oxygen. The patient is free to ambulate and can continue with normal daily living activities while being treated 24 hours per day. EPIFLO® can be worn near the wound beneath clothing without impairing its operation. EPIFLO® extracts oxygen from the air, concentrates it to near 100%, and "pumps" the oxygen through the cannula to blanket the wound. The wound is covered with a fully occlusive dressing of the provider's choice. The dressing does not inflate and the patient has no sensation of air movement. EPIFLO® provides a silent, continuous, slow flow of oxygen (3 ml/hr for 15 days) that will not dry out the wound.
- TransCu O2® wound care device or EO_2 system (EO2 Concepts®) is a portable oxygen delivery system that provides a continuous flow of oxygen to a wound. Through a dressing attached to the device, oxygen is provided directly to the wound for 24 hours per day, 7 days a week. Oxygen is an important part in the wound healing process. The EO_2 system employs a TransCu O2® device, which uses fuel cell technology to continuously generate pure humidified oxygen at adjustable flow rates from 3-15 ml/hr and delivers it directly to the wound bed environment within the OxySpur® dressing. The OxySpur® Oxygen Diffusion Dressing is an all-in-one dressing for medium to high exudating wounds. Its design allows distribution of

oxygen over the entire wound.

- O2Boot® and O2Sacral® (GWR Medical, Inc) are portable and 1-time use devices applied and secured to the body by a hypo-allergenic adhesive seal. The area surrounding the wound receives 100% oxygen at 1.03 atm for 90 min for 4 consecutive days, followed by 3 days without treatment. The weekly treatment regimen is self-administered in the patient's home and continued as directed by the healthcare provider.

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