UnitedHealthcare Oxford

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Clinical Policy

Hyperbaric Oxygen Therapy And Topical Oxygen Therapy

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Instructions for Use

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Related Policies
None

Coverage Rationale

Hyperbaric Oxygen Therapy (HBOT) is proven and medically necessary for the following conditions:

- Acute traumatic peripheral ischemia/insufficiency (i.e. crush injury, reattachment of severed limbs, compartment syndrome)
- Air or gas embolism
- Anemia, severe, when transfusion is refused, delayed, or unavailable
- Carbon monoxide poisoning
- Central retinal artery occlusion
- Chronic osteomyelitis, refractory to medical and surgical management
- Clostridial myonecrosis (gas gangrene)
- Compromised skin grafts/flaps
- Cyanide poisoning, associated with carbon monoxide poisoning
- Decompression sickness
- Delayed radiation injuries (soft tissue and bony necrosis)
- Diabetic lower extremity wounds
- Idiopathic sudden sensorineural hearing loss (ISSHL)
- Intracranial abscess
- Necrotizing soft tissue infections
- Thermal burns, second, or third degree

Hyperbaric Oxygen Therapy is unproven and not medically necessary due to insufficient evidence of efficacy for treating and managing ALL other indications not listed above as proven.

Topical Oxygen Therapy (TOT) is unproven and not medically necessary for the treatment of wounds or ulcers due to insufficient evidence of efficacy.

Definitions

Hyperbaric Oxygen Therapy (HBOT): An intervention in which an individual breathes near 100% oxygen intermittently while inside a hyperbaric chamber that is pressurized to greater than sea level pressure (one atmosphere absolute [ATA]). For clinical purposes, the pressure must equal or exceed 1.4 ATA while breathing near 100% oxygen. In certain circumstances HBOT represents the primary treatment modality while in others it is an adjunct to surgical or pharmacologic interventions. (Undersea and Hyperbaric Medical Society, 2019)

Topical Oxygen Therapy (TOT): The direct application of oxygen to a wound site. TOT can be applied intermittently to an open wound at slightly above atmospheric pressure or applied continuously through a cannula secured under a wound dressing covered by film. (ECRI, 2021)

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

CPT Code	Description
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session

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HCPCS Code	Description
A4575	Topical hyperbaric oxygen chamber, disposable
E0446	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval

Diagnosis Codes
Hyperbaric Oxygen Therapy: Diagnosis Code List

Description of Services

Hyperbaric Oxygen (HBO) Therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure. Clinical treatments may be carried out in either a Class A (multi) or B (mono) chamber system. To meet the definition of Hyperbaric Oxygen Therapy, pressurization must be at least 1.4 atmospheres with inhalation of 100% oxygen. In a Class B system, the entire chamber is pressurized with near 100% oxygen, and the patient breathes the ambient chamber oxygen directly. A Class A system holds two or more people; the chamber is pressurized with compressed air while the patients breathe near 100% oxygen via masks, head hoods, or endotracheal tubes. It is important to note that Class B systems can and are pressurized with compressed air while the patients breathe near 100% oxygen via masks, head hoods, or endotracheal tubes (Indications for Hyperbaric Oxygen Therapy. Undersea and Hyperbaric Medical Society. Available at: https://www.uhms.org/images/UHMS-Reference-Material.pdf. (Accessed February 17, 2023)

Topical Oxygen Therapy is the direct application of oxygen to the wound site. Adequate blood flow to a wound provides necessary oxygen and nutrients for tissue regeneration, but in some wounds blood flow is inadequate and the wound is hypoxic. The metabolic demands generated by tissue healing alone may cause hypoxia. TOT has been proposed as a potential way to oxygenate tissue in a hypoxic wound. Clinicians apply oxygen directly to the wound site at slightly above atmospheric pressure. If the wound is on an appendage, that limb can be surrounded by a sealed plastic bag; wounds in other anatomic sites may be covered with a plastic bag that has sealed edges. Another approach is to use a TOT device that continuously provides oxygen to the wound through a cannula secured under a wound dressing covered by film. (ECRI, 2019)

Clinical Evidence

Acute Traumatic Peripheral Ischemia/Insufficiency

Eskes et al. (2013) conducted a Cochrane systematic review to determine the effects of HBOT on the healing of acute surgical and traumatic wounds. The review included four RCTs (n = 229 participants) comparing HBOT with other interventions such as dressings, steroids, or sham or comparisons between alternative HBOT regimens. The studies precluded a meta-analysis because they were clinically heterogeneous. One trial (48 participants with burn wounds undergoing split skin grafts) compared HBOT with usual care and reported a significantly higher complete graft survival associated with HBOT. A second trial (ten participants in free flap surgery) reported no significant difference between graft survival (no data available). A third trial (36 participants with crush injuries) reported significantly more wounds healed, and significantly less tissue necrosis with HBOT compared to sham HBOT. The fourth trial (135 people undergoing flap grafting) reported no significant differences in complete graft survival with HBOT compared with dexamethasone or heparin. The authors concluded there was a lack of high quality, valid research evidence regarding the effects of HBOT on wound healing; however, two small trials suggested that HBOT may improve the outcomes of skin grafting and trauma. The authors recommend further high-quality clinical trials that assess the effects of HBOT on wound healing.

A systematic review of nine studies involving 150 patients who underwent HBO as an adjunct treatment for acute traumatic ischemia and crush injury found that eight of the nine studies showed a beneficial effect from HBO with only one major complication. The authors concluded that HBO could be beneficial if administered early, but well-designed studies are needed to evaluate this form of therapy. (Garcia-Covarrubias et al., 2005)

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

The 10th annual ECHM consensus on hyperbaric medicine recommends HBOT for the treatment of open fractures and/or with crush injury. Additionally, the consensus states it would be reasonable to provide HBOT for closed crush injuries where tissue viability is at risk, and for where there is a potential for compartment syndrome where compartment syndrome requiring fasciotomy is not established and where it is possible to monitor progress and response to treatment. (Mathieu et al., 2017)

Undersea and Hyperbaric Medical Society (UHMS)

UHMS state clinical findings coupled with accepted grading systems should be used to make decisions to use HBOT for crush injuries. The UHMS indication for using HBOT for crush injuries is that the injury severity is so great that the survival of deep tissues and/or skin flaps is threatened. Early application of HBOT, preferably within four to six hours of the injury is recommended. UHMS also recommends HBOT for skeletal muscle-compartment syndrome and acute traumatic ischemia. (UHMS, 2019)

Air Embolism or Gas Embolism

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

ECHM recommends HBOT in the treatment of gas embolism, arterial and venous gas embolism with neurological and/or cardiac manifestations. Even if a short interval (< 6h) between embolism and hyperbaric treatment is associated with a better outcome, response to HBOT with substantial clinical improvement has been observed in many case reports with a longer interval and even in small series of patients after 24 hours or more. (Mathieu, 2017)

Undersea and Hyperbaric Medical Society (UHMS)

UHMS recommends HBOT for arterial gas embolism and symptomatic venous gas embolism. (UHMS, 2019)

Anemia

Clinical Practice Guidelines

Undersea and Hyperbaric Medical Society (UHMS)

UHMS states HBOT should be considered in severe anemia when patients cannot receive blood products for medical, religious, strong personal preferential reasons, or situational blood availability. HBOT use should be guided by the patient's calculated accumulating oxygen debt rather than by waiting for signs or symptoms of systemic or individual end-organ failure. HBOT should be considered as a bridge therapy until severe life-threatening acute anemia can be resolved. (UHMS, 2019)

Carbon Monoxide (CO) Poisoning

Lin et al. (2018) conducted a systematic review and meta-analysis of RCTs evaluating HBOT and its effect on neuropsychometric dysfunction after CO poisoning. Six studies were included that compared HBOT with normobaric oxygen (NBO) in patients with CO poisoning. Compared with patients treated with NBO, a lower percentage of patients treated with HBO reported headache, memory impairment, difficulty concentrating, and disturbed sleep. Two sessions of HBO treatment exhibited no advantage over one session. The authors concluded HBO treated patients have a lower incidence of neuropsychological sequelae when compared with CO poisoning patients treated with NBO. Limitations include small sample sizes of the included studies.

In a Cochrane review, Buckley et al. (2011) evaluated RCTs of HBO therapy compared to NBO therapy, involving adults who are acutely poisoned with CO. Six randomized controlled trials of varying quality were identified involving 1361 participants, two of the trials found a beneficial effect of HBO for the reduction of neurologic sequelae at one month, while four others did not. The authors concluded that existing randomized trials do not establish whether the administration of HBO to patients with CO poisoning reduces the incidence of adverse neurologic outcomes. The authors stated that the results should be interpreted cautiously due to the significant methodologic and statistical heterogeneity of the trials. According to the authors, additional research is needed to better define the role, if any, of HBO in the treatment of patients with CO poisoning.

In a randomized trial, Hopkins et al. (2007) found that HBOT reduces cognitive sequelae after CO poisoning in the absence of the epsilon 4 allele. The apolipoprotein (APOE) epsilon 4 allele predicts unfavorable neurologic outcome after brain injury and stroke. Because apolipoprotein genotype is unknown at the time of poisoning, the investigators recommend that patients with acute CO poisoning receive HBOT.

Clinical Practice Guidelines

American College of Emergency Physicians (ACEP)

A clinical policy on management of CO poisoning published by the ACEP states that emergency physicians should use HBOT or high-flow normobaric therapy for acute CO poisoned patients. It remains unclear whether HBOT is superior to normobaric oxygen therapy for improving long-term neurocognitive outcomes. (Wolf et al., 2017)

European Committee for Hyperbaric Medicine (ECHM)

The ECHM recommends HBOT in the treatment of any CO poisoned person as a first aid treatment, CO poisoned pregnant women whatever their clinical presentation and carboxyhemoglobin level at hospital admission, and CO poisoned patients who present with altered consciousness alteration, clinical neurological, cardiac, respiratory or psychological signs whatsoever the carboxyhemoglobin level at the time of hospital admission. For those patients with minor CO poisoning, ECHM considers it reasonable to treat either by 12 hours normobaric oxygen or HBOT. (Mathieu et al, 2017)

Undersea and Hyperbaric Medical Society (UHMS)

UHMS states for patients with CO poisoning treated with HBOT, both mortality and neurocognitive morbidity are improved beyond that expected with ambient pressure supplemental oxygen therapy with the optimal benefit occurring in those treated with the least delay after exposure. (UHMS, 2019)

Central Retinal Artery Occlusion

Wu et al. (2018) conducted a meta-analysis to determine the effectiveness of oxygen therapy in retinal artery occlusion patients. The primary endpoint was visual acuity (VA). Seven RCTs met inclusion criteria. Patients who received oxygen therapy exhibited probability of visual improvement about 5.61 times compared with the control group who did not receive oxygen therapy. No statistically significant difference was observed between oxygen inhalation methods, combined therapy, or RAO type. Conversely, 100% oxygen and hyperbaric oxygen significantly improved VA in RAO patients. Better effect was showed in period within three months and the most effective treatment length was over nine hours. The authors concluded that oxygen therapy had beneficial effects in improving VA in RAO patients, especially when treated with 100% hyperbaric oxygen for over nine hours.

Clinical Practice Guidelines

American Academy of Ophthalmology (AAO)

AAO states current evidence for effective interventional treatment for central retinal artery occlusion, is controversial; however, the use of HBOT (100% oxygen over nine hours) has demonstrated efficacy over observation alone in several small, randomized trials. (Flaxel et al, 2020)

European Committee for Hyperbaric Medicine (ECHM)

The ECHM suggests considering HBOT for patient's suffering from central retinal artery occlusion, to be applied as soon as possible. (Mathieu et al, 2017)

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS recommends HBOT for patients with central retinal artery occlusion. The authors note that patients particularly at risk include those with giant cell arteritis, atherosclerosis, and thromboembolic disease and wide variety of treatment modalities have been tried over the last one hundred years with little to no success, with the exception of HBOT. UHMS recommends patient presenting within twenty-four hours of symptom onset should be considered for HBOT and patients who present with sudden painless loss of vision due to central retinal artery occlusion should be triaged as "emergent" because of the need for immediate oxygen therapy. Hyperbaric oxygen can be delivered for 90 minutes at the depth of return of vision, with a maximum of a U.S. Navy Treatment Table 6 (USNTT6) for the first treatment. The optimum number of treatments will vary depending on the severity and duration of the patient's symptoms and the degree of response to treatment. (UHMS, 2019)

Chronic Osteomyelitis

Goldman (2009) completed a systematic review for wound healing and limb salvage. The authors identified 121 citations for hyperbaric oxygen for treating osteomyelitis. Of these, 15 citations listed original observational studies; 14 reported positive findings, and one study, equivocal findings. Including data reported in all 15 abstracts, the median remission rate (defined most consistently as resolution of drainage) was 89% of patients (range, 37-100%) for follow-up as long as 63 months, for 309 patients reported over 15 studies. On full review, five studies rated moderate strength of evidence, six low, and four very low. The investigators concluded that there is a moderate level of evidence that HBO therapy promotes healing of refractory osteomyelitis.

A retrospective study was conducted to evaluate 13 patients with chronic refractory osteomyelitis of the femur who were treated with adjunctive HBO. Twelve of the 13 patients had complete eradication of infection with no recurrence. One patient did not respond to treatment. (Chen et al., 2004)

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

The ECHM suggests HBOT be used in the treatment of refractory osteomyelitis. Additionally, HBOT treatments should last at least 11 to 12 weeks, approximately sixty sessions, before any significant clinical effect should be expected, and the effects of HBOT should be evaluated repeatedly during and after treatment. (Mathieu et al, 2017)

Undersea and Hyperbaric Medical Society (UHMS)

UHMS supports the use of HBOT as a beneficial adjunct in the management of refractory osteomyelitis; the highest-reported osteomyelitis cure rates were obtained when HBOT was combined with culture-directed antibiotics and concurrent surgical debridement. (UHMS, 2019)

Clostridial Myonecrosis (Gas Gangrene)

Clinical Practice Guidelines

Undersea and Hyperbaric Medical Society (UHMS)

UHMS states the preferred treatment for clostridial myositis and myonecrosis (gas gangrene) or spreading clostridial cellulitis with systemic toxicity (or presumptive diagnosis of either), is a combination of HBOT, surgery and antibiotics. (UHMS, 2019)

Compromised Skin Grafts/Flaps

Spruijt et al. (2021) conducted a retrospective analysis to evaluate outcomes of HBOT in the patients with mastectomy flap ischemia. Fifty breasts requiring HBOT were included in the review. The skin ischemia necrosis (SKIN) score was used to evaluate the severity of the ischemia or necrosis. HBOT was started a median of three days (range 1-23) after surgery and continued for a median of 12 sessions (range 6-22). The breast SKIN surface area scores (n = 175 observations by the independent observers) improved in 34% (of observations) and the depth scores deteriorated in 42% (both $p < 0.01$). Both the surface area and depth scores were associated with the need for re-operation: higher scores, reflecting more severe necrosis of the mastectomy flap, were associated with increased need for re-operation. Twenty-nine breasts (58%) recovered without additional operation. Pre-operative radiotherapy and postoperative infection were risk factors for re-operation in multivariate analyses. The authors concluded HBOT decreased the surface area of the breast affected by ischemia. The authors state future RCTs are needed to confirm or refute HBOT improves outcomes in patients with mastectomy flap ischemia.

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

ECHM suggest using HBOT in the treatment of all cases of compromised skin grafts and flaps, as soon as possible after the diagnosis of compromised grafts/tissues. The treatment suggested by ECHM is HBOT at a pressure between 203 and 253 kPa for at least 60 minutes per session, repeated two to three times in first day, then twice per day or once daily until tissues are declared alive or necrotic. HBOT is recommended for both pre-and post-operatively in cases when there is an increased risk for compromised skin grafts and flaps. (Mathieu et al, 2017)

Undersea and Hyperbaric Medical Society (UHMS)

UHMS recommends HBOT in tissue compromised by irradiation, in flap salvage, or in other cases where there is decreased perfusion or hypoxia. Additionally, criteria for selecting the proper patients that are likely to benefit from adjunctive HBOT, and identification of the underlying cause for graft or flap compromise are crucial for a successful outcome. To be maximally effective, HBOT should be started as soon as signs of flap or graft compromise appear. (UHMS, 2019)

Cyanide Poisoning

Clinical Practice Guidelines

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS Indications for HBOT website (2019) states carbon monoxide and cyanide poisoning frequently occur simultaneously in victims of smoke inhalation and in combination, these two agents exhibit synergistic toxicity. HBOT is recommended as an adjunct to the treatment of combined carbon monoxide poisoning complicated by cyanide poisoning. (UHMS, 2019)

Decompression Sickness

In a Cochrane review, Bennett et al. (2012a) examined the safety and efficacy of both recompression therapy (hyperbaric oxygen therapy) and adjunctive therapies for the treatment of decompression illness (DCI). Two RCTs with a total of 268 patients were included in the review. In one study there was no evidence of improved effectiveness with the addition of a non-steroidal anti-inflammatory drug (tenoxicam) to routine recompression therapy (at six weeks: relative risk (RR) 1.04, 95% confidence interval (CI) 0.90 to 1.20, $p = 0.58$) but there was a reduction in the number of compressions required when tenoxicam was added from three to two ($p = 0.01$, 95% CI 0 to 1). In the other study, the odds of multiple recompressions were lower with a helium and oxygen (heliox) table compared to an oxygen treatment table (RR 0.56, 95% CI 0.31 to 1.00, $p = 0.05$). The authors concluded neither the addition of a non-steroidal anti-inflammatory drug or the use of heliox improved the odds of recovery but may reduce the number of recompressions required. Additionally, while recompression therapy is the standard of care for treatment of DCI, there is no RCT evidence for its use.

Hyperbaric oxygen (HBO) therapy is widely accepted as standard care for treating life threatening conditions such as decompression illness and air or gas embolism for which there are limited alternative treatment options. (Raman et al., 2006)

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

The 10th annual ECHM consensus on hyperbaric medicine recommends HBOT in the treatment of decompression illness. (Mathieu et al., 2017)

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS recommends HBOT for decompression sickness stating HBOT use is widely accepted and the mainstay of treatment for this disease. (UHMS, 2019)

Delayed Radiation Injury

Meier et al. (2023) conducted a systematic review on the effect of HBOT on symptoms of local late radiation toxicity (LRT) in breast cancer patients. Nine studies (1308 patients) reporting the effect of HBOT for symptoms of LRT following radiotherapy of the breast and/or chest wall were included. Pain, lymphedema, skin problems/necrosis, arm and shoulder mobility, arm and breast symptoms, and fibrosis were the toxicity outcomes evaluated. Post-HBOT, a significant reduction of pain was observed in four out of five studies, of fibrosis in one in two studies, and of lymphedema of the breast and/or arm in four out of seven studies. Skin problems of the breast were significantly reduced in one out of two studies, arm and shoulder mobility significantly improved in two out of two studies, and breast and arm symptoms were significantly reduced in one study. The authors concluded that although evidence is limited, HBOT might be useful for reducing symptoms of LRT in breast cancer patients. The authors recommend future RCTs including a combination of patient- and clinician- reported outcomes. Limitations include a lack of a control group in most studies and small sample sizes.

A 2021 ECRI Clinical Evidence Assessment focused on HBOT's safety and effectiveness for preventing or treating delayed radiation injuries in patients who previously underwent radiotherapy. The assessment included two RCTs and six systematic reviews which indicated HBOT was safe and improved outcomes for patients with assorted clinical indications. HBOT was found to improve mucosal healing and reduce wound breakdown, improve dental implant survival after head and neck radiotherapy, and promotes cystitis and proctitis symptom resolution. ECRI reports evidence for HBOT used in delayed radiation injury as somewhat favorable.

Bennett et al. (2016) conducted a systemic review and meta-analysis of RCTs comparing the effect of HBOT versus no HBOT on late radiation tissue injury (LRTI) healing or prevention. The study was comprised of 14 trials with a total of 753 participants. There was some moderate quality evidence that HBOT was more likely to achieve mucosal coverage with osteoradionecrosis and of a significantly improved chance of wound breakdown without HBOT following operative treatment for osteoradionecrosis. From single studies there was a significantly increased chance of improvement or cure following HBOT for radiation proctitis and following both surgical flaps, and hemimandibulectomy. There was also a significantly improved probability of healing irradiated tooth sockets following dental extraction. There was no evidence of benefit in clinical outcomes with established radiation injury to neural tissue, and no randomized data reported on the use of HBOT to treat other manifestations of LRTI. The authors concluded that HBOT is associated with improved outcomes for patients with LRTI affecting tissues of the head, neck, anus, and rectum. Additionally, HBOT appears to reduce the chance of osteoradionecrosis following tooth extraction in an irradiated field. The authors recommend further research to establish optimum timing and patient selection.

Hampson et al. (2012) report the collected outcomes from 411 patients who underwent hyperbaric oxygen to treat chronic radiation injury. A positive clinical response was defined as an outcome graded as either "resolved" (90%-100% improved) or "significantly improved" (50%-89% improved). A positive outcome from hyperbaric treatment occurred in 94% of patients with osteoradionecrosis of the jaw (n = 43), 76% of patients with cutaneous radionecrosis that caused open wounds (n = 58), 82% of patients with laryngeal radionecrosis (n = 27), 89% of patients with radiation cystitis (n = 44), 63% of patients with gastrointestinal radionecrosis (n = 73), and 100% of patients who were treated in conjunction with oral surgery in a previously irradiated jaw (n = 166). The authors concluded that the outcomes of 411 patients strongly supported the efficacy of hyperbaric oxygen treatment for the six conditions evaluated. According to the authors, the response rates previously reported in numerous small series were corroborated by the response rates achieved in this large, single-center experience.

Freiberger et al. (2009) evaluated the long-term outcomes in 65 consecutive patients meeting a uniform definition of mandibular osteoradionecrosis (ORN) treated with multimodality therapy including hyperbaric oxygen (HBO). Pretreatment, post-treatment and long-term follow-up of mandibular lesions with exposed bone were ranked by a systematic review of medical records and patient telephone calls. In all, 57 cases (88%) resolved or improved by lesion grade or progression and evolution criteria after HBO. Four patients healed before surgery after HBO alone. Of 57 patients who experienced improvement, 41 had failed previous non-multimodality therapy for three months and 26 for six months or more. A total of 43 patients were eligible for time-to-relapse survival analysis. Healing or improvement lasted a mean duration of 86.1 months in nonsmokers (n = 20) vs. 15.8 months in smokers (n = 14) versus 24.2 months in patients with recurrent cancer (n = 9). The investigators concluded that multimodality therapy using HBO is effective for ORN when less intensive therapies have failed.

A prospective study evaluated the impact of perioperative HBO therapy on the quality of life (QOL) of irradiated maxillofacial patients; 1 group of patients (n = 28) was referred for treatment of ORN, which included debridement of necrotic tissue and perioperative HBO; the second group (n = 38) were dental patients referred for therapy to prevent ORN resulting from dental extraction or intraoral implant placement within an irradiated field. Results in both groups suggested that the combination of HBO and surgery contributed to an improved QOL and psychological status in this patient population. (Harding et al., 2008)

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

The 10th annual ECHM consensus on hyperbaric medicine recommends HBOT in the treatment of mandibular osteoradionecrosis, the prevention of mandibular osteoradionecrosis after dental extraction, and treatment of hemorrhagic radiation cystitis and proctitis. HBOT is suggested for preventing loss of osseointegrated implants in irradiated bone, and treatment of soft tissue radionecrosis (other than cystitis and proctitis). ECHM states it would be reasonable to use HBOT for treating or preventing radio-induced lesions of the larynx, or central nervous system. (Mathieu et al., 2017)

Undersea and Hyperbaric Medical Society (UHMS)

UHMS states delayed radiation injury for soft tissue and bony necrosis is the most frequent indication for HBOT and requires a multidisciplinary approach, especially when bone is involved. Characteristically, most courses for radiation injury will be in the range of thirty to sixty hyperbaric treatments when the course is carried out with daily treatments at 2.0 to 2.5 ATA for 90-120 minutes. (UHMS, 2019)

Diabetic Lower Extremity Wounds

Sharma et al. (2022) conducted a systematic review and meta-analysis to assess the efficacy of HBOT on diabetic foot ulcers. The study included RCTs and other sources that evaluated the effect of HBOT on diabetic foot ulcer, mortality rate, complete healing, adverse events, amputation, and ulcer reduction area. Fourteen studies (768 participants) including twelve RCTs, and two controlled clinical trials were included. The results with pooled analysis have shown that HBOT was significantly effective in complete healing of diabetic foot ulcer (OR = 0.29; 95% CI 0.14-0.61; I2 = 62%) and reduction of major amputation (RR = 0.60; 95% CI 0.39-0.92; I2 = 24%). HBOT was not effective for minor amputations (RR = 0.82; 95% CI 0.34-1.97; I2 = 79%); however, less adverse events were reported in the standard treatment group (RR = 1.68; 95% CI 1.07-2.65; I2 = 0%). Reduction in mean percentage of ulcer area and mortality rate did not differ in HBOT and control groups. The authors concluded that HBOT was associated with lower major amputation rates, higher rates of healed DFUs, and HBOT as an adjunctive treatment measure for the diabetic foot ulcer, is effective. Limitations include that only six of 14 trials included performed sample size calculations, and the duration and techniques used in HBOT while treating patients were not uniform in most of the studies. The authors recommend HBOT should be used with caution when treating DFUs, and future multicentric trials to assess efficacy and safety of HBOT as an adjunct treatment for DFUs are needed.

A (2021) ECRI Clinical Evidence Assessment compared HBOT's safety and effectiveness for improving chronic diabetic foot ulcer healing and preventing amputation, with standard care alone. The assessment included one systematic review with meta-analysis of controlled trials, a technology assessment reporting on quality of life and costs, and four additional RCTs. It was concluded that HBOT improves ulcer healing rates and may reduce the need for major amputations in patients with chronic diabetic foot ulcers.

In a Cochrane review, Kranke et al. (2015) conducted a systematic review and meta-analysis of RCTs that compared the effect on chronic wound healing of therapeutic regimens which include HBOT with those that exclude HBOT (with or without sham therapy). Twelve trials (577 participants) where included in the review. Ten trials (531 participants) enrolled people with a diabetic foot ulcer: pooled data of five trials with 205 participants showed an increase in the rate of ulcer healing with HBOT at six weeks but this benefit was not evident at longer-term follow-up at one year. There was no statistically significant difference in major amputation rate. One trial (16 participants) considered venous ulcers and reported data at six weeks (wound size reduction) and 18 weeks (wound size reduction and number of ulcers healed) and suggested a significant benefit of HBOT in terms of reduction in ulcer area only at six weeks. One trial (30 participants) which enrolled patients with non-healing diabetic ulcers as well as venous ulcers ("mixed ulcer types") and patients were treated for 30 days. For this "mixed ulcers" there was a significant benefit of HBOT in terms of reduction in ulcer area at the end of treatment (30 days). No trials were identified that considered arterial and pressure ulcers. The authors concluded individuals that HBOT significantly improved the ulcers healed in the short term but not the long term. The authors state the trials reviewed had various flaws and recommended future trials to evaluate HBOT in people with chronic wounds.

Londahl et al. (2011) evaluated whether circulatory variables could help in predicting outcome of HBOT. All Diabetic Patients with Chronic Foot Ulcers (HODFU) study participants who completed therapy, predefined as receiving at least 36 out of 40 scheduled HBOT/placebo sessions, were included in this study (n = 75). Baseline transcutaneous oximetry (TcPO2), toe blood pressure (TBP) and ankle-brachial index (ABI) were measured. Ulcer healing rate was registered at the 9-month follow-up visit. An ulcer was considered healed when it was completely epithelialized and remained so at the 12-month follow-up. In the HBOT group TcPO2 were significantly lower for patients whose ulcer did not heal as compared with those whose ulcers healed. A significantly increased healing frequency was seen with increasing TcPO2 levels in the HBOT group. No statistically significant relation between the level of TBP or ABI and healing frequency was seen. According to the investigators, the result of this study indicates that TcPO2 in contrast to ABI and TBP correlates to ulcer healing following HBOT. The investigators suggest HBOT as a feasible adjunctive treatment modality in diabetic patients with chronic non-healing foot ulcers when basal TcPO2 at the dorsum of the foot is above 25 mmHg.

A study by Kaya et al. (2008) was completed to evaluate whether hyperbaric oxygen can decrease major amputation rates. A total of 184 consecutive patients were treated with hyperbaric oxygen therapy as an adjunct to standard treatment modalities for their diabetic foot ulcer. Of these patients, 115 were completely healed, 31 showed no improvement and 38 underwent amputation. The investigators concluded that hyperbaric oxygen therapy can help reduce the major amputation rates in diabetic foot ulcer.

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

The 10th annual ECHM consensus on hyperbaric medicine recommends using HBOT in the treatment of ischemic lesions (ulcers or gangrene) without surgically treatable arterial lesions or after vascular surgery. The use of HBOT in the diabetic patient and the arteriosclerotic patient is recommended in the presence of a chronic critical ischemia. (Mathieu et al., 2017)

National Institute for Health and Clinical Excellence (NICE)

In a diabetic foot problems clinical guideline, NICE (2015), recommended that HBO not be offered for treatment of diabetic foot ulcers unless part of a clinical trial.

Society for Vascular Surgery (SVS)/American Podiatric Medical Association (APMA)/Society for Vascular Medicine (SVM)

In an evidence-based multidisciplinary management approach, the SVS in collaboration with the APMA and the SVM developed a clinical practice guideline designed to improve the care of patients with diabetic foot. The guideline states that for DFUs that fail to demonstrate improvement (> 50% wound area reduction) after a minimum of four weeks of standard wound therapy, adjunctive wound therapy options, including HBOT are recommended. In patients with DFU who have adequate perfusion that fails to respond to four to six weeks of conservative management, HBOT is suggested. (Hingorani et al. 2016)

Undersea and Hyperbaric Medical Society (UHMS)

UHMS recommends HBOT for patients with Wagner Grade 3 or higher diabetic foot ulcers (DFU) that have not shown significant improvement after 30 days of treatment, to reduce the risks of major amputation and incomplete healing. In patients with Wagner Grade 3 or higher DFUs who have just had a surgical debridement of an infected foot, postoperative HBOT added to standard wound care in order to reduce the risk of major amputation is also recommended. HBOT is not suggested for patients with Wagner Grade 2 or lower DFUs. (UHMS, 2019)

Idiopathic Sudden Sensorineural Hearing Loss (ISSHL)

Cavaliere et al. (2022) conducted a RCT to compare the effect of HBOT, oral steroids (OS) and a combination of both therapies (HBOT+OS) for treating sudden sensorineural hearing loss (SSNHL). One hundred and seventy-one patients with SSNHL were randomized and included in the study. Participants were evaluated by pure tone audiometry test (PTA) at baseline and 20 days after treatment. After baseline PTA, patients were randomly assigned to each group, HBOT-group A, OS-group B, and HBOT+OS-group C. Patients in the HBOT+OS, and HBOT groups improved their auditory function ($p < 0.05$). HBOT was the best choice for treatment when started by seven days from SSNHL onset, while HBOT+OS in case of late treatment. Profound SNHL recovered equally by HBOT, and HBOT+OS ($p < 0.05$). Upsloping SNHL obtained better auditory results by HBOT compared to HBOT+OS ($p < 0.05$). Downsloping and flat SSNHL had the most improvement with HBOT+OS compared to HBOT only ($p < 0.05$). The authors concluded that in both early and late treatment, a combination of HBOT and OS is a valid treatment for SSNHL and had the best results. Limitations include lack of a control group.

Joshua et al. (2022) conducted a systematic review and meta-analysis of RCTs to evaluate the use of HBOT with hearing outcomes in patients with SSNHL and determine if HBOT should be utilized as a single treatment or part of the combination regimen. The study included 3 RCTs, 88 patients who received HBOT in intervention groups and 62 patients who had routine treatment in the control group. The intergroup difference in mean absolute hearing gain (mean difference, 10.3 dB; 95% CI, 6.5-14.1 dB; $I2 = 0\%$) and the odds ratio of hearing recovery (4.3; 95% CI, 1.6-11.7; $I2 = 0\%$) favored HBOT over the control therapy. The authors suggest that HBOT as part of a combination treatment regimen should be considered for patients with SSNHL. Limitations include small sample sizes of studies, and the secondary outcome (adverse effect of treatment) could not be assessed. The authors recommend further studies to assess the adverse effects of treatment and to determine the optimal HBOT protocol.

Rhee et al. (2018) conducted a systematic review and meta-analysis that compared HBOT and medical treatment (MT) with MT alone as treatment for patients with ISSHL. PubMed, Embase, and the Cochrane Database of Systematic Reviews were systematically searched up to February 2018. The study included three RCTs and 16 nonrandomized studies for a total of 2401 patients with ISSHL. Pooled odds ratios (ORs) for complete hearing recovery and any hearing recovery were significantly higher in the HBOT+MT group than in the MT alone group. Absolute hearing gain was also significantly greater in the HBOT+MT group than in the MT alone group. The benefit of HBOT was greater in groups with severe to profound hearing loss at baseline, HBOT as a salvage treatment, and a total HBOT duration of at least 1200 minutes. The authors concluded that particularly for those patients with severe to profound hearing loss at baseline, and those who undergo HBOT as a salvage treatment with a prolonged duration, adding HBOT to standard MT is a reasonable treatment option. The authors note further trials using well-defined indications and standardized protocols of HBOT are warranted.

Bennett et al. (2012b) updated a Cochrane Review first published in 2005 and previously updated in 2007 and 2009 that was conducted to assess the benefits and harms of HBOT for treating ISSHL. Seven randomized studies ($n = 392$ total participants) comparing the effect of HBOT and alternative therapies on tinnitus and ISSHL were included. Pooled data from two trials did not show any significant improvement in the chance of a 50% increase in hearing threshold on pure-tone average with HBOT, but did show a significantly increased chance of a 25% increase in pure-tone average. There was a 22% greater chance of improvement with HBOT, and the number needed to treat to achieve one extra good outcome was five. There was also an absolute improvement in average pure-tone audiometric threshold following HBOT. The significance of any improvement in tinnitus could not be assessed. There were no significant improvements in hearing or tinnitus reported for chronic presentation (six months) of ISSHL and/or tinnitus. The authors concluded the application of HBOT significantly improved hearing for people with acute ISSHL, but the clinical significance remains unclear. The authors note the studies were small and of poor quality; future RCTs to define what patients would derive most benefit from HBOT was recommended.

Clinical Practice Guidelines

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

In an AAO-HNS 2019 clinical practice guideline sudden hearing loss update initial therapy with HBOT was recommended when combined with steroid therapy within two weeks of onset of SSNHL. Additionally, HBOT was recommended when combined with steroid therapy as salvage within one month of onset of SSNHL. (Chandrasekhar et al, 2019)

European Committee for Hyperbaric Medicine (ECHM)

ECHM recommends HBOT in the treatment of acute ISSHL combined with medical therapy in patients who present within two weeks of disease onset. Additionally, the ECCHM states it would be reasonable to use HBOT as an adjunct to corticosteroids in patients presenting after the first two weeks but not later than one month, especially, in those with severe and profound hearing loss. (Mathieu et al., 2017)

Undersea and Hyperbaric Medical Society (UHMS)

UHMS includes sudden sensorineural hearing loss as a recommended indication for HBOT for patients with moderate to profound ISSHL (≥ 40 dB) who present within 14 days of symptom onset. The authors note that while patients presenting after this time may experience improvement when treated with HBOT, the medical literature suggests that early intervention is associated with improved outcomes and the best evidence supports the use of HBOT within two weeks of symptom onset. (UHMS, 2019)

Intracranial Abscess

Bartek et al. (2016) evaluated HBOT in the treatment of intracranial abscesses in a population-based, comparative cohort study that included 40 adult patients with spontaneous brain abscess treated surgically between January 2003 and May 2014. Twenty patients (non-HBOT group) received standard therapy with surgery and antibiotics, while the remaining 20 patients (HBOT group) also received adjuvant HBOT. All patients had resolution of brain abscesses and infection. Two patients had reoperations after HBOT initiation (10 %), while nine patients (45 %) in the non-HBOT group underwent reoperations. Of the twenty-six patients who did not receive HBOT after the first surgery, fifteen (58 %) had one or several recurrences that lead to a new treatment: surgery (n = 11), surgery + HBO (n = 5) or just HBO (n = 1). In contrast, recurrences occurred in only two of fourteen (14 %) who did receive HBOT after the first surgery. A good outcome (Glasgow Outcome Score [GOS] of 5) was achieved in sixteen patients (80 %) in the HBOT cohort versus nine patients (45 %) in the non-HBOT group. The authors concluded HBOT was well tolerated, safe, was associated with less treatment failures and need for reoperation, and appeared to have improved long-term outcome. The authors state future prospective studies are warranted to establish the role of HBOT in brain abscess treatment. Limitations include the retrospective nature of the study and small study size.

Kutlay et al. (2008) evaluated the effect of adjuvant hyperbaric oxygen (HBO) therapy on the duration of antibiotic treatment. The study included 13 patients (mean age of 43.9 years) with bacterial brain abscesses treated with stereotactic aspiration combined with HBO and systemic antibiotic therapy. Postoperatively, all patients were given a 4-week course of intravenous antibiotics. Additionally, patients received hyperbaric oxygen (100% O2 at 2.5 ATA for 60 min) twice daily for five consecutive days, and an additional treatment (100% O2 at 2.5 ATA for 60 min daily) was given for 25 days. The average duration of follow-up was 9.5 months. Infection control and healing occurred in all 13 patients with 0% recurrence rate. HBO treatment was tolerated well, and there were no adverse effects of pressurization. At the end of the follow-up period, 12 patients had a good outcome: nine are without sequelae, and three have a mild hemiparesis but are capable of self-care. One patient has a moderate hemiparesis. The authors stated that although the number of patients is small, this series represents the largest reported group of brain abscess patients treated with stereotactic aspiration combined with antibiotic and HBO therapy. According to the authors, the preliminary results of this study indicate that the length of time on antibiotics can be shortened with the use of HBO as an adjunctive treatment.

Clinical Practice Guidelines

Undersea and Hyperbaric Medical Society (UHMS)

UHMS recommends adjunct HBOT for intracranial abscess for patients with multiple abscesses, abscesses in deep or dominant location, compromised host, in situations where surgery is contraindicated/poor surgical risk, and when there is no response or further deterioration in spite of standard surgical and antibiotic treatment. Per UHMS, early in the diagnosis, it is prudent to involve a multidisciplinary team to direct management including neurosurgery, neurology and infectious disease. (UHMS, 2019)

Necrotizing Infections

Hedetoft et al. (2021) conducted a systemic review and meta-analysis of the evidence to support or refute the use of HBOT in treatment of necrotizing soft-tissue infections (NSTI). The primary outcome was in-hospital mortality. Thirty-one studies were included in the qualitative synthesis and twenty-one in the meta-analyses. Meta-analysis on 48,744 patients with NSTI (1,237 (2.5%) HBOT versus 47,507 (97.5%) non-HBOT) showed in-hospital mortality was 4,770 of 48,744 patients overall (9.8%) and the pooled odds ratio (OR) was 0.44 (95% CI 0.33–0.58) in favor of HBOT. For major amputation the pooled OR was 0.60 (95% CI 0.28–1.28) in favor of HBOT. The dose of oxygen in these studies was incompletely reported. The authors concluded patients with NSTI treated with HBOT may be less likely to require a major amputation and have a reduced odds of dying during a sentinel event. Additionally, the authors note the most effective dose of oxygen remains uncertain in terms of treatment profile, the optimal interval between treatments, and the total number of treatments required for the optimal outcome. The authors endorse future high quality RCTs.

In a Cochrane systematic review, Levett et al. (2015) reviewed the evidence of HBOT use as an adjunctive treatment for patients with necrotizing fasciitis (NF) to determine if HBOT reduced mortality or morbidity associated with NF and if there were adverse effects associated with HBOT in treatment of NF. The selection criteria included all randomized and pseudo-randomized trials comparing effects of HBOT with the effects of no HBOT in NF. No trials were found that met inclusion criteria that would support or refute the effectiveness of HBOT in NF treatment. The authors recommend future, good quality, RCTs.

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

The 10th annual ECHM consensus on hyperbaric medicine recommends HBOT for the treatment of necrotizing soft tissue infections in all locations, particularly perineal gangrene. (Mathieu et al., 2017)

Undersea and Hyperbaric Medical Society (UHMS)

UHMS recommends HBOT for necrotizing fasciitis stating there is strong case series evidence of reductions in patient morbidity and mortality. Furthermore, strongest consideration should be given to patients who are compromised hosts, as they are likely to do worse with their infection. (UHMS, 2019)

World Society of Emergency Surgery (WSES)

The WSES guideline for management of skin and soft tissue infections states that although the benefit of adjuvant HBOT remains controversial, it may be considered where it is available as there is a trend in clinical outcomes which shows that HBOT may be useful in managing NSTI. The authors recommend future robust RCTs. (Sartelli et al, 2014)

Thermal Burns, Second or Third Degree

In a 2004 Cochrane review, Villanueva et al. assessed the evidence for the benefit of HBOT in the treatment of thermal burns. Four RCTs collected from Cochrane, MEDLINE, CINAHL, EMBASE and DORCTHIM that compared the effect of HBOT with no HBOT (no treatment or sham) where identified, of which two satisfied the inclusion criteria. The authors note the trials were of poor methodological quality. The authors concluded the systematic review did not find sufficient evidence to refute or support the effectiveness of HBOT for thermal burns and recommended future research.

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

The 10th annual ECHM consensus on hyperbaric medicine suggests HBOT for the treatment of second degree burns > 20% body surface area (BSA); burns to the face, neck , hands, perineum may benefit even if the total surface burned is < 20%. Furthermore, ECHM recommends that only specialized HBOT centers in the immediate vicinity of a burns center treat burns as an adjunct to classical burn care. (Mathieu et al., 2017)

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS states HBOT of burns is recommended for patients with a burn that is 20% or greater total body surface area (TBSA), and/or hands, face, feet, or perineum. Treatment must be directed toward minimizing edema, preserving marginally viable tissue, protecting the microvasculature, enhancing host defenses, and promoting wound closure. The authors state adjunctive HBOT is recommended as it can benefit each of these problems directly. (UHMS, 2019)

Unproven Conditions

Due to insufficient evidence of safety and/or efficacy, the following are unproven and not medically necessary. Future robust, quality studies are needed.

There is no reliable data from well-designed clinical studies that report HBOT is effective for other conditions, including but not limited to, COVID-19 related illnesses, Autism Spectrum Disorder, Alzheimer's disease, cancer, sickle cell anemia, depression, and other psychiatric disorders, or delayed milestones. Further quality studies are needed to assess the benefits of HBOT for these conditions.

Topical Oxygen Therapy (TOT)

An ECRI Clinical Evidence Assessment (2021) evaluating the safety and efficacy TOT for treating DFU compared with standard of care, such as debridement, moisture balance maintenance with dressing, and infection control found that TOT added to the standard of care appeared to increase DFU healing more than the standard of care alone. The assessment notes that to determine the best TOT application method and how TOT compares to other treatments, additional RCTs are needed.

He et al. (2021) conducted a single-center RCT to determine the effect of continuous diffusion of oxygen (CDO) combined with traditional moist wound dressing (MWD) on the DFUs of inpatients. Participants were randomly divided into three groups consisting of 40 patients each. One group received the moist dressing, one group was treated with a micro-oxygen supply device and one group received a combination of moist dressing and a micro-oxygen supply device. Amputation rate, wound healing, and inflammatory control were evaluated after 8 weeks of treatment. Compared with MWD and CDO groups, the combination group showed a higher wound healing rate ($p < 0.05$), lower white blood cell count ($p < 0.05$) and lower high-sensitivity C-reactive protein level ($p < 0.05$). During 1-year follow-up, the amputation rate was 0% in combination group, which was significantly lower than that in other two groups ($p < 0.05$). The authors concluded the combination treatment of MWD and CDO was effective in preventing infection and promoting healing of DFUs. Limitations include a small sample size and lack of molecular mechanism exploration. The authors recommend larger, randomized, double-blinded studies in the future.

Blackman et al. (2010) conducted a prospective, controlled study to examine the clinical efficacy of a pressurized TOT (TWO(2)) device in outpatients (n = 28) with severe diabetic foot ulcers referred for care to a community wound care clinic and to assess ulcer reoccurrence rates after 24 months. Seventeen patients received TWO(2) five times per week (60-minute treatment, pressure cycles between five and 50 mb) and 11 selected a silver-containing dressing changed at least twice per week (control). Patient demographics did not differ between treatment groups but wounds in the treatment group were more severe, perhaps as a result of self-selection bias. Ulcer duration was longer in the treatment (mean 6.1 months, SD 5.8) than in the control group (mean 3.2 months, SD 0.4) and mean baseline wound area was 4.1 cm2 (SD 4.3) in the treatment and 1.4 cm2 (SD 0.6) in the control group. Fourteen of 17 ulcers (82.4%) in the treatment group and five of 11 ulcers (45.5%) in the control group healed after a median of 56 and 93 days, respectively. No adverse events were observed and there was no reoccurrence at the ulcer site after 24 months' follow-up in either group. According to the investigators, although the absence of randomization and blinding may have under- or overestimated the treatment effect of either group, the significant differences in treatment outcomes confirm the potential benefits of TWO(2) in the management of difficult-to-heal diabetic foot ulcers. Further clinical efficacy studies as well as studies to evaluate the mechanisms of action of topical oxygen therapy are warranted.

A parallel observational comparative study included patients who were managed with either topical wound oxygen (n = 46) or conventional compression dressings (CCD) (n = 37) for 12 weeks or until full healing. At 12 weeks, 80% of topical oxygen-managed wound ulcers were completely healed, compared to 35% of CCD ulcers. Median time to full healing was 45 days in topical wound oxygen patients and 182 days in CCD patients. The pain score threshold in topical wound oxygen managed patients improved from eight to three by 13 days. After 12-month follow-up, five of the 13 healed CCD ulcers showed signs of recurrence compared to none of the 37 topical wound oxygen healed ulcers. Limitations of this study included its small sample size, and non-randomization of study participants. (Tawfick and Sultan, 2009)

Clinical Practice Guidelines

The International Working Group on the Diabetic Foot (IWGDF)

The IWGDF guideline states that TOT should not be used as a primary or adjunctive intervention in DFU including those that are difficult to heal. (Rayman, 2020)

Undersea and Hyperbaric Medical Society (UHMS)

UHMS states that application of topical oxygen cannot be recommended routine clinical treatment due to a restricted volume and quality of supporting, scientific evidence. Before topical oxygen can be recommended as therapy for non-healing wounds, its application should be subjected to additional scientific scrutiny to better establish indications for use, response to treatment, and dosing. (UHMS, 2018)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Hyperbaric oxygen chambers are classified as Class II devices according to the FDA. Many hyperbaric chambers that are used in wound healing have been approved via the FDA 501(k) process. Refer to the following Web site for more information: Use product code CBF (hyperbaric chamber). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed February 17, 2023)

FDA conditions for which hyperbaric chambers are cleared for marketing:

- Air and gas bubbles in blood vessels
- Anemia (severe anemia when blood transfusions cannot be used)
- Burns (severe and large burns treated at a specialized burn center)
- Carbon monoxide poisoning
- Crush injury
- Decompression sickness (diving risk)
- Gas gangrene
- Hearing loss (complete hearing loss that occurs suddenly and without any known cause)
- Infection of the skin and bone (severe)
- Radiation injury
- Skin graft flap at risk of tissue death
- Vision loss (when sudden and painless in one eye due to blockage of blood flow)
- Wounds (non-healing, diabetic foot ulcers)
- HBOT is being studied for other conditions, including COVID-19. However, at this time, the FDA has not cleared or authorized the use of any HBOT device to treat COVID-19 or any conditions beyond those listed above. The website, clinicaltrials.gov, has more information on HBOT clinical trials for COVID-19 and other conditions.

Refer to the following Web site for more information: https://www.fda.gov/consumers/consumer-updates/hyperbaric-oxygen-therapy-get-facts. (Accessed February 17, 2023)

Adverse events for hyperbaric chambers are reported in the FDA Manufacturer and User Facility Device Experience (MAUDE) database. For information on adverse events reported on hyperbaric chambers, refer to the following (insert CBF into the Product Code field): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM. (Accessed February 17, 2023)

Topical Oxygen Therapy devices are regulated by the FDA as Class II devices and several devices have been approved via the FDA 510(k) process. Refer to the following Web site for more information (use product code KPJ): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed February 17, 2023)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2023T0632B]

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Policy History/Revision Information

Date	Summary of Changes
06/01/2023	**Definitions** • Removed definition of "Continuous Topical Oxygen Therapy (CTOT)" **Applicable Codes** • Revised description for ICD-10 diagnosis codes I70.238 and I70.248 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version OUTPATIENT 051.2

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

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