Hyperbaric Oxygen Therapy and Topical Oxygen Therapy

Policy Number: 2025T0632H
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Instructions for Use

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Related Commercial/Individual Exchange Policies
None

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

Hyperbaric Oxygen Therapy (HBOT) is 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
- Avascular necrosis (aseptic osteonecrosis)
- 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

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

Mild Hyperbaric Oxygen Therapy (mHBOT) is unproven and not medically necessary for any indication due to insufficient evidence of efficacy.
Note: This device does not meet the definition of HBOT.

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 (UHMS), 2023].

Mild Hyperbaric Oxygen Therapy (mHBOT): Low-pressure fabric hyperbaric chambers are specialized devices designed to be compressed using only air. These chambers deliver oxygen at pressures lower than 1.4 ATA. They have received FDA 510(k) clearance specifically for the treatment of acute mountain sickness (UHMS, 2018).

Topical Oxygen Therapy (TOT): The direct application of oxygen to a wound site. Topical Oxygen Therapy 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 and Guidelines 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 and Topical Oxygen Therapy: Diagnosis Code List

Description of Services

Hyperbaric Oxygen Therapy (HBOT) involves exposing the entire body to oxygen at increased atmospheric pressure. This treatment can be administered in either a Class A (multi) or B (mono) chamber system. To meet the definition of HBOT, the pressure 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 individual breathes the ambient chamber oxygen directly. The Class A system accommodates two or more people. In this configuration, the chamber is pressurized with compressed air while the individuals breathe near 100% oxygen via masks, head hoods, or endotracheal tubes. It is important to note that Class B systems can also be pressurized with compressed air, in which case individuals would similarly breathe nearly 100% oxygen via masks, head hoods, or endotracheal tubes [Undersea and Hyperbaric Medical Society (UHMS), 2023].

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Mild Hyperbaric Oxygen Therapy (mHBOT) is the use of fabric zippered bags which deliver no more oxygen to the body than the use of a mask at sea level pressure. It provides mild compression of less than 1.4 atmosphere absolute (ATA) and is FDA cleared for treating altitude sickness only (UHMS, 2023).

Topical Oxygen Therapy (TOT) 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. Topical Oxygen Therapy 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

Hyperbaric Oxygen Therapy (HBOT)

Acute Traumatic Peripheral Ischemia/Insufficiency

Kwee et al. (2024) performed a systematic review of the existing literature aimed to assess the efficacy of HBOT in treatment of severe soft tissue injuries of the lower limbs caused by crush injuries. The review included seven studies (n = 229) comprised of two randomized controlled trials (RCTs), one retrospective cohort study, one case report, and three case series. Individuals who received HBOT in addition to standard trauma care for crush-associated severe lower limb soft tissue injuries met the inclusion criteria. The randomized placebo-controlled clinical trial showed a significant increase in wound healing and decrease in the need for additional surgical interventions in the group receiving HBOT when compared to those undergoing sham therapy. The randomized non-placebo controlled clinical trial revealed that early HBOT reduces tissue necrosis and the likelihood of long-term complications. The retrospective cohort study indicated that HBOT effectively reduces infection rates and the need for additional surgical interventions. The case series and case report presented beneficial results with regard to wound healing when HBOT was added to the treatment regimen. The authors concluded HBOT is a safe and effective treatment option and when used alongside standard trauma care, HBOT appeared to enhance wound healing in cases of severe soft tissue injuries in the lower limbs. Limitations included the relatively small sample size and the lack of long-term follow-up data.

In a retrospective review, Takagi et al. (2024) evaluated whether HBOT would enhance outcomes for chronic limb-threatening ischemia (CLTI) and explored the therapeutic effects of repetitive HBOT for those with CLTI that were not candidates for revascularization. Individuals (n = 58) were eligible for inclusion if they had CLTI, confirmed through angiography or contrast-enhanced computed tomography, which suggested lower-limb arterial occlusion, with rest pain or refractory leg ulcers that did not improve with standard treatment. Individuals eligible for revascularization in poor general health were excluded from the study. The mean age was 71 ±13 years. Of all patients, 67% had diabetes and 43% were undergoing hemodialysis. The mean follow-up period was 4.3 ±0.8 years. The overall survival rate was 84.5% and 81.0% at one and three years, respectively. The Cox regression analysis indicated that high body mass index (odds ratio [OR]: 0.86; 95% confidence interval [CI]: 0.76 - 0.97; p = 0.01), well-nourished (OR: 1.21; 95% CI:1.01 - 1.45), and HBOT (OR: 0.05; 95% CI: 0.01 - 0.26; p < 0.001) independently predicted absence of major adverse events. For major limb amputation, the ankle-brachial index (OR: 0.2; 95% CI: 0.05 - 0.86; p = 0.03) and HBOT (OR: 0.04; 95% CI: 0.004 - 0.32; p = 0.003) were independent predictors. The authors concluded repetitive HBOT may significantly contribute to major adverse events-free survival and enhance the likelihood of limb salvage. Limitations included the retrospective nature of the study.

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 recommended further high-quality clinical trials that assess the effects of HBOT on wound healing.

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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). The UHMS updated manual for HBOT indications continued to recommend HBOT for acute traumatic ischemias (UHMS, 2023).

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 (less than six hours) 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; updated 2023).

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). The UHMS updated manual for HBOT indications continued to recommend HBOT for severe anemia (UHMS, 2023).

Avascular Necrosis (AVN) (Aseptic Osteonecrosis)

Moghamis et al. (2021) conducted a retrospective cohort study to compare outcomes of core decompression versus HBOT in stage II non-traumatic avascular necrosis AVN of the femoral head. Nineteen individuals with 23 non-traumatic stage II AVN of the femoral head that were confirmed by MRI were included in the study, 11 in the HBOT group and 12 in the core decompression group. 66.7% of individuals in core decompression and 81.8% in the HBOT group achieved satisfactory hip function outcome with statistically significant mean Oxford Hip Score (35.8 ±6.7 and 35.5 ±5.1) (P 0.009 & .003), respectively. No statistical difference of Oxford Hip Score and Short-Form12 (Physical Component Summary [PCS] & Mental Component Summary [MCS]) was found between the two groups (P 0.202, 0.128 & .670 respectively). Eight (34.7%) cases progressed to a higher radiological stage at one year follow-up. The rate of progression was not statistically significant between both groups (P 0.469) with no statistical difference of Oxford Hip Score and Short-Form12 (PCS & MCS) in the progressed group (P 0.747, 0.648 & 0.416), respectively. The authors concluded that in treatment of non-traumatic pre-collapsed AVN of the femoral head, HBOT is as effective as core decompression and could be used as an alternative non-invasive treatment option. Limitations included small sample size and the retrospective design of the study. The authors recommended future large RCTs to compare short-and long-term outcomes.

Paderno et al. (2021) conducted a systematic review and meta-analysis aimed to clarify the clinical effects of HBOT in treating femoral head necrosis (FHN). Ten cohort studies published prior to May 2020 consisting of 368 HBOT cases were included in the study. General clinical improvement (pain reduction, change in range of hip motion, physical and

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mental relief) and specific improvement at MRI were evaluated in the studies. The clinical effect in the HBOT group was 3.84 times higher than in the control group (OR = 3.84, 95% CI (2.10, 7.02), p < 0.00001). Subgroup analyses showed that the clinical effect of HBOT was statistically significant in the Asian subpopulation which represented most of the subjects (OR = 3.53, 95% CI (1.87, 6.64), p < 0.00001), but not in the non-Asian subpopulation, probably because of insufficient numerosity (OR = 7.41, 95% CI (0.73, 75.71), p = 0.09). The authors concluded that individuals with FHN treated at early stages with HBOT achieved a significant clinical improvement. The authors noted that limitations include the constraints imposed by the quality and quantity of research and future large-sample RCTs are recommended.

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

The ECHM suggests the use of HBOT in the initial stage of FHN. The committee recommends HBOT should be part of a multidisciplinary plan and not used as an isolated treatment (Mathieu et al, 2017).

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS recommends HBOT for use with AVN in the early stages of the disease (Ficat I and II), and in the pre-collapse stage of articulation (Ficat III, early stage) (UHMS, 2023).

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 individuals with CO poisoning. Compared with individuals treated with NBO, a lower percentage of individuals treated with HBOT reported headache, memory impairment, difficulty concentrating, and disturbed sleep. Two sessions of HBOT exhibited no advantage over one session. The authors concluded individuals treated with HBOT have a lower incidence of neuropsychological sequelae when compared with CO poisoning individuals treated with NBO. Limitations included small sample sizes of the included studies.

In a Cochrane review, Buckley et al. (2011) evaluated RCTs of HBOT compared to NBO therapy, involving adults who are acutely poisoned with CO. Six RCTs of varying quality were identified involving 1361 participants, two of the trials found a beneficial effect of HBOT 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 HBOT to individuals 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 HBOT in the treatment of individuals 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 four allele. The apolipoprotein (APOE) epsilon four allele predicts unfavorable neurologic outcome after brain injury and stroke. Because APOE genotype is unknown at the time of poisoning, the investigators recommended that participants with acute CO poisoning receive HBOT.

Clinical Practice Guidelines

American College of Emergency Physicians (ACEP)

An updated clinical policy on management of CO poisoning published by the ACEP states that for symptomatic CO poisoning, selected patients may benefit from HBOT based on the severity of symptoms and availability (distance and time). The potential benefit is noted as improved neurologic outcomes (Shih et al., 2025).

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 NBO 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

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treated with the least delay after exposure (UHMS, 2019). The UHMS updated manual for HBOT indications continued to recommend HBOT for CO poisoning (UHMS, 2023).

Central Retinal Artery Occlusion

Wu et al. (2018) conducted a meta-analysis to determine the effectiveness of oxygen therapy in retinal artery occlusion individuals. The primary endpoint was visual acuity (VA). Seven RCTs met inclusion criteria. Individuals 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 individuals with RAO. 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 individuals with RAO, 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, retrospective studies. (Kovach et al., 2025).

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 six (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). The UHMS updated manual for HBOT indications continued to recommend HBOT for central retinal artery occlusion (UHMS, 2023).

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 individuals (range, 37 - 100%) for follow-up as long as 63 months, for 309 individuals 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 HBOT promoted healing of refractory osteomyelitis.

A retrospective study was conducted to evaluate 13 individuals with chronic refractory osteomyelitis of the femur who were treated with adjunctive HBOT. Twelve of the 13 individuals had complete eradication of infection with no recurrence. One individual 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

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concurrent surgical debridement (UHMS, 2019). The UHMS updated manual for HBOT indications continued to recommend HBOT for refractory osteomyelitis (UHMS, 2023).

Clostridial Myonecrosis (Gas Gangrene)

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

The ECHM recommends HBOT be integrated in a treatment protocol combined with surgery and antibiotics targeting the most probable anaerobic and aerobic involved bacteria (Mathieu et al, 2017).

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). The UHMS updated manual for HBOT indications continues to recommend HBOT for gas gangrene (UHMS, 2023).

Compromised Skin Grafts/Flaps

ECRI (2023) developed an assessment of HBOT for compromised skin grafts and flap salvage that reports the available clinical evidence on how and when to use HBOT for compromised skin grafts and flaps is insufficient to determine how well this intervention works to improve outcomes. The quality of evidence is too low to be conclusive, but some studies indicated a possible benefit to graft survival after HBOT.

Spruijt et al. (2021) conducted a retrospective analysis to evaluate outcomes of HBOT in the individuals 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 one to 23) after surgery and continued for a median of 12 sessions (range six to 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 stated future RCTs are needed to confirm or refute HBOT improves outcomes in individuals 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 kilopascal (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 recommended 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). The UHMS updated manual for HBOT indications continues to recommend HBOT for compromised grafts and flaps (UHMS, 2023).

Cyanide Poisoning

Clinical Practice Guidelines

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS Indications for HBOT website (2019) states CO 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 CO poisoning complicated by cyanide poisoning. (UHMS, 2019). The UHMS updated manual for HBOT indications continues to recommend HBOT for cyanide poisoning (UHMS, 2023).

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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. Two RCTs with a total of 268 individuals 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% 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 decompression illness, there is no RCT evidence for its use.

Hyperbaric oxygen 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). The UHMS updated manual for HBOT indications continues to recommend HBOT for decompression sickness (UHMS, 2023).

Delayed Radiation Injury

Yang et al. (2024) conducted a systematic review and meta-analysis to evaluate the safety and efficacy of HBOT for treatment of radiation-induced hemorrhagic cystitis (RHC). Fourteen studies with 556 participants were included in the review. Studies with primary outcomes of complete remission and partial remission in individuals with RHC treated with HBOT were included. Those with previous definitive therapy for cancer in non-pelvic areas, individuals with radiation cystitis not treated with HBOT, and non-English studies were excluded. Complete resolution of hematuria was the primary endpoint. The results showed that a total of 500 individuals (89.9%) had symptom improvement, and the pooled results demonstrated that 55% of individuals with HBOT had complete remission of hematuria (95% CI 51 - 59%). The authors concluded that individuals with RHC treated with HBOT showed significant improvement in symptoms. Limitations included the lack of prospective studies or RCTs and the small sample sizes.

Meier et al. (2023) conducted a systematic review on the effect of HBOT on symptoms of local late radiation toxicity (LRT) in individuals with breast cancer. Nine studies (1308 individuals) 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 of 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 individuals with breast cancer. The authors recommended future RCTs including a combination of patient- and clinician-reported outcomes. Limitations included 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 those who previously underwent radiotherapy. The assessment included two RCTs and six systematic reviews which indicated HBOT was safe and improved outcomes for individuals 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 (ECRI, 2021).

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

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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 individuals 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 recommended further research to establish optimum timing and participant selection. In a 2023 update of the original Cochrane review published in July 2005 and previously updated in 2012 and 2016, Lin et al. assessed the benefits and risks of HBOT for treating or preventing late radiation tissue injury, comparing it to treatment regimens that did not include HBOT. Four new studies were added to this update which included 1071 participants. The authors concluded that there is some evidence suggesting that HBOT may improve outcomes in LRTI affecting both bone and soft tissues of the head and neck, as well as the bladder and lower bowel. Additionally, HBOT may help reduce wound breakdown and alleviate pain following LRTI. However, HBOT did not impact the short-term mortality risk in the individuals studied. Generally, HBOT is considered safe and well-tolerated, though there is a risk of temporary short-sightedness due to oxygen exposure and potential ear drum injury during compression. Limitations included small sample sizes, and poor reporting of methods and results.

Hampson et al. (2012) report the collected outcomes from 411 individuals 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 individuals with osteoradionecrosis of the jaw (n = 43), 76% of individuals with cutaneous radionecrosis that caused open wounds (n = 58), 82% of individuals with laryngeal radionecrosis (n = 27), 89% of individuals with radiation cystitis (n = 44), 63% of individuals with gastrointestinal radionecrosis (n = 73), and 100% of individuals who were treated in conjunction with oral surgery in a previously irradiated jaw (n = 166). The authors concluded that the outcomes of 411 individuals 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 individuals meeting a uniform definition of mandibular osteoradionecrosis treated with multimodality therapy including hyperbaric oxygen. Pretreatment, post-treatment, and long-term follow-up of mandibular lesions with exposed bone were ranked by a systematic review of medical records and telephone calls. In all, 57 cases (88%) resolved or improved by lesion grade or progression and evolution criteria after HBO. Four individuals healed before surgery after HBOT alone. Of 57 individuals who experienced improvement, 41 had failed previous non-multimodality therapy for three months and 26 for six months or more. A total of 43 individuals 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 individuals with recurrent cancer (n = nine). The investigators concluded that multimodality therapy using HBOT is effective for osteoradionecrosis when less intensive therapies have failed.

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

Clinical Practice Guidelines

American Society of Colon and Rectal Surgeons (ASCRS)

Paquette et al. (2018) published a clinical practice guideline for the ASCRS, indicating that HBOT is an effective treatment modality for reducing bleeding in individuals with chronic radiation proctitis (Strong recommendation based on moderate-quality evidence, 1B).

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

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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 conducted with daily treatments at 2.0 to 2.5 atmosphere absolute (ATA) for 90 - 120 minutes (UHMS, 2019). The UHMS updated manual for HBOT indications continued to recommend HBOT for delayed radiation injury (UHMS, 2023).

Diabetic Lower Extremity Wounds

Tao et al. (2024) performed a systematic review and meta-analysis to evaluate the efficacy and safety of HBOT in the treatment of diabetic foot ulcers (DFUs). The inclusion criteria for the study included participants in RCTs diagnosed with DFUs who were undergoing HBOT, either as a standalone treatment or in conjunction with other treatments. The control group received standard care protocols. The primary and secondary outcomes measured included the complete wound healing rate, efficacy rate, incidence of amputations, changes in ulcer surface area, and any adverse reactions experienced. Seven RCTs met the inclusion criteria. HBOT was found to significantly improve the complete healing rates of DFUs with a RR of 3.59 (95% CI: 1.56 - 8.29, $p < 0.001$). However, HBOT's impact on both major and minor amputation rates did not yield statistically significant results. The sensitivity analysis underscored the robustness of the principal outcomes, and the publication bias assessment suggested the absence of any significant bias. The authors concluded that HBOT is a highly effective therapeutic approach that significantly enhances the healing process of DFUs and promotes effective wound resolution, while also demonstrating commendable safety profiles. Limitations included small samples sizes of some of the studies, selections bias where participants were not randomly selected, and the absence of long-term follow-up.

Sharma et al. (2022) conducted a systematic review and meta-analysis to assess the efficacy of HBOT on DFUs. The study included RCTs and other sources that evaluated the effect of HBOT on DFU, 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 DFU (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 DFU, 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 individuals 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.

In a systematic review and meta-analysis, Zhang et al. (2022) evaluated the efficacy of HBOT for DFU treatment. Twenty RCTs met inclusion criteria and were included in the study. HBOT increased the healing rate of DFUs (relative risk, 1.901; 95% CI = 1.484 - 2.435, $p < 0.0001$), shortened the healing time (mean difference = -19.360; 95% CI = 28.753 ~ -9.966, $p < 0.001$), and reduced the incidence of major amputation (relative risk, 0.518, 95% CI = 0.323 - 0.830, $p < 0.01$). The authors concluded HBOT has considerable benefit in healing DFU and decreasing amputation rate. The authors recommended future RCTs to evaluate the efficacy of HBOT for healing DFU. Londahl et al. (2011) which was previously cited in this policy was included in this study.

A (2021) ECRI Clinical Evidence Assessment compared HBOT's safety and effectiveness for improving chronic DFU 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 QOL and costs, and four additional RCTs. It was concluded that HBOT improves ulcer healing rates and may reduce the need for major amputations in individuals with chronic DFUs.

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 DFU: 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

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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 individuals with non-healing diabetic ulcers as well as venous ulcers ("mixed ulcer types") and individuals 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 stated the trials reviewed had various flaws and recommended future trials to evaluate HBOT in people with chronic wounds.

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

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).

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).

International Working Group on the Diabetic Foot (IWGDF)

The IWGDF guideline states that systemic HBOT can be used as an adjunctive treatment in ischemic ulcers that fail to heal after four to six weeks despite optimal clinical care and resources are available to support the intervention (Schaper et al. 2023).

Undersea and Hyperbaric Medical Society (UHMS)

UHMS recommends HBOT for patients with Wagner Grade 3 or higher 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). The UHMS updated manual for HBOT indications continued to recommend HBOT for DFUs (UHMS, 2023).

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 participants 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, participants were randomly assigned to each group, HBOT-group A, OS-group B, and HBOT + OS-group C. Participants 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 included 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 individuals with SSNHL and determine if HBOT should be utilized as a single treatment or part of the combination regimen. The study included three RCTs, 88 individuals who received HBOT in intervention groups and 62

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individuals 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 individuals with SSNHL. Limitations included small sample sizes of studies, and the secondary outcome (adverse effect of treatment) could not be assessed. The authors recommended 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 individuals 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 individuals with ISSHL. Pooled 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 individuals 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 noted 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 remained unclear. The authors noted the studies were small and of poor quality; future RCTs to define what individuals 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 SSNHL 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). The UHMS updated manual for HBOT indications continued to recommend HBOT for ISSHL (UHMS, 2023).

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 individuals with spontaneous brain abscess treated surgically between January 2003 and May 2014. Twenty individuals (non-HBOT group) received standard therapy with surgery and antibiotics, while the remaining 20 individuals (HBOT group) also received adjuvant HBOT. All individuals had resolution of brain abscesses and infection. Two individuals had reoperations after HBOT initiation (10%), while nine individuals (45%) in the non-HBOT group underwent reoperations. Of the twenty-six individuals 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 + HBOT (n = five) or just HBOT (n =

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one). 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 five) was achieved in sixteen individuals (80%) in the HBOT cohort versus nine individuals (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 stated future prospective studies are warranted to establish the role of HBOT in brain abscess treatment. Limitations included the retrospective nature of the study, and small study size.

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

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

The 10th annual ECHM consensus on hyperbaric medicine recommends HBOT for the treatment of intra-cranial abscess for one or more of the following: multiple abscesses; abscess in a deep or dominant location; compromised host; contraindication to surgery, lack of response, or further deterioration with standard treatment (Mathieu et al., 2017).

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). The UHMS updated manual for HBOT indications continued to recommend HBOT for intracranial abscess (UHMS, 2023).

Necrotizing Infections

In a systematic review and meta-analysis, Huang et al. (2023) aimed to assess the impact of HBOT on the clinical outcomes of necrotizing soft tissue infections (NSTI). A total of twenty-three retrospective cohort and case-control studies met inclusion criteria, including 1448 individuals who received HBOT and 47,704 in control. Mortality rate was the primary outcome. Number of debridements, amputation rate, and complication rate were secondary outcomes. The mortality rate in the HBOT group was significantly lower than that in the non-HBOT group [RR = 0.522, 95% CI (0.403, 0.677), $p < 0.05$]. However, the number of debridements performed in the HBOT group was higher than in the non-HBOT group [SMD = 0.611, 95% CI (0.012, 1.211), $p < 0.05$]. There was no significant difference in amputation rates between the two groups [RR = 0.836, 95% CI (0.619, 1.129), $p > 0.05$]. In terms of complications, the incidence of MODS was lower in the HBOT group than in the non-HBOT group [RR = 0.205, 95% CI (0.164, 0.256), $p < 0.05$]. There was no significant difference in the incidence of other complications, such as sepsis, shock, myocardial infarction, pulmonary embolism, and pneumonia, between the two groups ($p > 0.05$). The authors concluded the use of HBOT significantly reduced the mortality rates and incidence rates of complications in the treatment of NSTI. Limitations included the duration and frequency of HBOT varied across the studies and retrospective nature of the studies. The authors recommended further research to establish efficacy.

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 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 individuals with NSTI (1,237 (2.5%) HBOT versus 47,507 (97.5%) non-HBOT) showed in-hospital mortality was 4,770 of 48,744 individuals overall (9.8%) and the pooled 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 individuals 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 noted the most effective dose of oxygen remains uncertain in terms

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of treatment profile, the optimal interval between treatments, and the total number of treatments required for the optimal outcome. The authors endorsed future high quality RCTs.

In a Cochrane systematic review, Levett et al. (2015) reviewed the evidence of HBOT use as an adjunctive treatment for individuals 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 recommended 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 NSTI in all locations, particularly perineal gangrene (Mathieu et al., 2017).

Undersea and Hyperbaric Medical Society (UHMS)

UHMS recommends HBOT for NF 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). The UHMS updated manual for HBOT indications continued to recommend HBOT for necrotizing infections (UHMS, 2023).

World Society of Emergency Surgery (WSES)/Global Alliance for Infections in Surgery (GAIS)/World Surgical Infection Society (WSIS)/American Association for the Surgery of Trauma (AAST)

The WSES/GAIS/WSIS//AAST global clinical pathway 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 but should not delay the standard treatment, and the patient should not be transferred to carry out HBOT thereby delaying critical care (Sartelli et al, 2022).

Thermal Burns, Second or Third Degree

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 greater than 20% body surface area (BSA); burns to the face, neck, hands, perineum may benefit even if the total surface burned is less than 20%. Furthermore, ECHM recommended 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 BSA, 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 stated adjunctive HBOT is recommended as it can benefit each of these problems directly (UHMS, 2019). The UHMS updated manual for HBOT indications continued to recommend HBOT for thermal burn injury (UHMS, 2023).

Other Indications

There are no reliable data from well-designed clinical studies that report HBOT is effective for other conditions. Further robust quality studies are needed.

Mild Hyperbaric Oxygen Therapy (mHBOT)

Conclusions of benefit for mHBOT are derived from animal studies, small, uncontrolled studies, or anecdotal reports. mHBOT does not significantly increase tissue oxygenation to therapeutic levels. The marginal increase in oxygen delivered at mild pressures may not be enough to produce statistically significant meaningful biological outcomes. Studies have not demonstrated benefits beyond placebo effect. Safety and regulatory concerns have been published for potentially delaying more effective and proven therapies. Currently, this device has only been approved by the U.S. Food and Drug Administration (FDA) for treatment of acute mountain sickness.

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Clinical Practice Guidelines

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS (2017) released a position statement regarding low-pressure fabric hyperbaric chambers that provide mHBOT. The position statement notes that mHBOT results in exposure to treatment pressures less than 1.4 ATA while breathing air and does not meet the definition of therapeutic HBOT. The low-pressure hyperbaric chambers do not achieve the minimum pressure and oxygen levels required for any UHMS-approved indication.

Topical Oxygen Therapy (TOT)

Quality evidence in peer-reviewed medical literature evaluating TOT is limited. Future robust RCTs are warranted along with long-term outcomes to establish the safety and efficacy of this treatment.

In a 2024 systematic review and meta-analysis, Putri et al. evaluated seven RCTs (n = 692) and two observational studies (n = 111) that compared supplemental TOT with standard wound care. The rate of healed wounds was 25.8% in the control group and 43.25% in the adjuvant TOT group, which showed the use of TOT significantly increased the number of healed wounds (RR = 1.77; 95% CI 1.18 - 2.64; p = 0.005). A significant decrease in the percentage of wound area was found in the TOT group in RCT studies (mean difference = 15.64; 95% CI 5.22 - 26.06; p = 0.003). In observational studies, the rate of healed wounds was 37.5% in the standard care group and 80.95% in the adjuvant TOT group, which shows a significant increase in the number of healed wounds in the adjuvant TOT group (RR = 2.15; 95% CI 1.46 - 3.15; p < 0.00001). The authors concluded that TOT is an effective adjunctive treatment for chronic wound healing, especially for wounds with vascular compromise, such as diabetic ulcers and pressure ulcers. However, the authors note that further research is needed to explore the potential applications of this technology across various types of wounds and for TOT as a main or sole treatment. Limitations included short follow-up periods and some of the studies has relatively small sample sizes. Tawfick and Sultan (2009), and Blackman et al. (2010) which were previously cited in this policy, are included in this review. He et al. (2021) is also included in this review.

Carter et al. (2023) conducted a systematic review and meta-analysis of four RCTs that compared adjunctive TOT with a control group of individuals receiving standard of care treatments (debridement, offloading, and moist wound care) for Wagner 1 and 2 DFUs. The primary outcome of interest was complete wound healing at 12 weeks, and secondary outcomes were wound-related pain, hospital readmissions, QOL, adverse effects, dependence or need for outside care, and adherence to the prescribed therapy. Risk of bias judgment (RoB2 analysis) resulted in one low-risk trial and three trials with some risk. One study was determined to be the origin of the statistical heterogeneity. Pooled results showed statistical significance with a RR of 1.59 (95% CI: 1.07 - 2.37; p = 0.021). Sensitivity analysis, based on imputed values for missing outcomes, demonstrated that both the RR and 95% CIs changed little. The GRADE ratings for each domain were as follows: (a) risk of bias: moderate (3); (b) imprecision: moderate (2), high (1); (c) inconsistency: low (2), high (1); (d) indirectness: moderate (2), high (1); and (e) publication bias: moderate (1), high (2). Overall, the evidence was noted as moderate. The authors concluded that in the absence of infection and ischemia, TOT was a viable treatment for Wagner 1 and 2 DFUs. Limitations included short term follow-up, small study size, and the confidence in the authors' conclusions may be limited by their stated financial conflicts of interest.

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 eight 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 one-year follow-up, the amputation rate was zero percent 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.

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Clinical Practice Guidelines

National Institute for Health and Care Excellence (NICE)

NICE (2020) performed an innovation briefing stating the Natrox device delivers 98% humidified oxygen directly and continuously to a wound through a flexible tube from a portable oxygen generator and is used to treat chronic non-healing wounds such as DFUs. The briefing included three studies that consisted of one small RCT and two larger observational studies. According to NICE, while the evidence showed that the Natrox device had an effect, the small sample sizes and heterogenous populations involved reduced the overall significance of the findings.

International Working Group on the Diabetic Foot (IWGDF)

The IWGDF guideline states that TOT can be used as an adjunctive treatment in non-infected ulcers that fail to heal after four to six weeks despite optimal clinical care and resources are available to support the intervention (Schaper et al. 2023).

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. According to the UHMS, 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 11, 2025.

Refer to the following web site for more information: https://www.fda.gov/consumers/consumer-updates/hyperbaric-oxygen-therapy-get-facts. Accessed February 11, 2025.

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 website (insert CBF into the Product Code field): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM. Accessed February 11, 2025.

Hyperbaric semi rigid chambers for low pressures (operating at pressures of 1.3 - 1.5 ATA) are classified as Class II devices according to the FDA. These devices were approved via the FDA 501(k) process and are intended to treat acute mountain sickness under the prescription of a health professional. Refer to the following website for more information (use product code CBF): https://www.accessdata.fda.gov/cdrh_docs/pdf22/K220290.pdf. Accessed February 27, 2025.

Note: The American Medical Association (AMA) released a Legislation and Regulation statement in 2022 noting their opposition to the 'mild hyperbaric facilities' unless effective treatments can be safely administered in facilities with appropriately trained staff, including physician supervision and prescription, and only when the intervention is scientifically supported. The AMA stated they would collaborate with the U.S. Food and Drug Administration and other regulatory bodies to shut down facilities offering "mild hyperbaric therapy" until they comply with all established safety regulations, adhere to the principles of hyperbaric oxygen practice under the prescription and oversight of a licensed and trained physician, and ensure that staff are properly trained and compliant with applicable safety regulations. Refer to the following website for more information: https://policysearch.ama-assn.org/policyfinder/detail/D-270.986?uri=%2FAMADoc%2Fdirectives.xml-D-270.986.xml. Accessed March 3, 2025.

Topical oxygen therapy (TOT) 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 11, 2025.

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Policy History/Revision Information

Date	Summary of Changes
07/01/2025	**Coverage Rationale** • Added language to indicate Mild Hyperbaric Oxygen Therapy (mHBOT) is unproven and not medically necessary for any indication due to insufficient evidence of efficacy; this device does not meet the definition of HBOT • Replaced language indicating "Hyperbaric Oxygen Therapy is unproven and not medically necessary due to insufficient evidence of efficacy for treating and managing all other indications not listed [in the policy] as *proven*" with "Hyperbaric Oxygen Therapy is unproven and not medically necessary due to insufficient evidence of efficacy for treating and managing all other indications not listed [in the policy]as *medically necessary*" **Definitions** • Added definition of "Mild Hyperbaric Oxygen Therapy (mHBOT)"

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Date	Summary of Changes
	Supporting Information • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version 2025T0632G

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare 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 reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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