Hyperbaric Oxygen Therapy and Topical Oxygen Therapy

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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 is medically necessary for the following conditions:

- Acute traumatic peripheral ischemia/insufficiency (e.g., 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
- 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 as medically necessary.

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

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

Definitions

Hyperbaric Oxygen Therapy: 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 [1 atmosphere absolute (ATA)]. For clinical purposes, the pressure must equal or exceed 1.4 ATA while breathing near 100% oxygen. In certain circumstances, Hyperbaric Oxygen Therapy represents the primary treatment modality, while in others, it is an adjunct to surgical or pharmacological interventions (Undersea and Hyperbaric Medical Society, 2023).

Mild Hyperbaric Oxygen Therapy: 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 U.S. Food and Drug Administration 510(k) clearance specifically for the treatment of acute mountain sickness (Undersea and Hyperbaric Medical Society, 2018).

Topical Oxygen Therapy: 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, 2019; updated 2025).

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 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 Hyperbaric Oxygen Therapy, 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, 2023).

Mild Hyperbaric Oxygen Therapy is the use of fabric zippered bags that 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 and is U.S. Food and Drug Administration cleared for treating altitude sickness only (Undersea and Hyperbaric Medical Society, 2023).

Topical Oxygen Therapy delivers oxygen directly to the wound surface to improve oxygenation in hypoxic tissue, particularly when local blood flow is inadequate. Using commercially available systems, oxygen is applied at slightly above atmospheric pressure within a sealed enclosure placed over the wound or affected limb. Treatment may consist of 90-minute sessions administered three to five times per week or continuous therapy. All wound dressings must be removed during application to allow effective transcutaneous oxygen delivery. Another approach uses a Topical Oxygen Therapy device that delivers continuous oxygen through a cannula positioned beneath a wound dressing and secured with an occlusive film (ECRI, 2019; updated 2025).

Clinical Evidence

Hyperbaric Oxygen Therapy

Acute Traumatic Peripheral Ischemia/Insufficiency

Kwee et al. (2024) performed a systematic review of the existing literature aimed to assess the efficacy of hyperbaric oxygen therapy (HBOT) in the treatment of severe soft tissue injuries of the lower limbs caused by crush injuries. The review included seven studies (n = 229), which comprised 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 compared with 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 that HBOT is a safe and effective treatment option; when it is used alongside standard trauma care, HBOT appeared to enhance wound healing in cases of severe soft tissue injuries in the lower limbs. Limitations include the relatively small sample size and lack of long-term follow-up data.

In a retrospective review, Takagi et al. (2024) evaluated whether HBOT would enhance outcomes of chronic limb-threatening ischemia (CLTI) and explored the therapeutic effects of repetitive HBOT in those with CLTI who were not candidates for revascularization. Patients (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. Patients who were eligible for revascularization and 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 1 and 3 years, respectively. The Cox regression analysis indicated that a high body mass index [odds ratio (OR), 0.86; 95% CI, 0.76-0.97; p = 0.01], being 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 the 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 that repetitive HBOT may significantly contribute to major adverse event–free survival and enhance the likelihood of limb salvage. Limitations include 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) that compared HBOT with other interventions such as dressings, steroids, or sham or compared it with alternative HBOT regimens. The studies precluded a meta-analysis because they were clinically heterogeneous. One trial (48 individuals 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 (10 individuals in free-flap surgery) reported no significant difference between graft survival (no data available). A third trial (36 individuals with crush injuries) reported significantly more wounds healed and significantly less tissue necrosis with HBOT compared with sham HBOT. The fourth trial (135 individuals undergoing flap grafting) reported no significant differences in complete graft survival with HBOT compared with dexamethasone or heparin. The authors concluded that there is a lack of high-quality, valid research evidence regarding the effects of HBOT on wound healing;

however, two small trials suggest 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.

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 with or without crush injury. Additionally, the consensus states that it would be reasonable to provide HBOT for closed crush injuries in which tissue viability is at risk; when there is a potential for compartment syndrome and compartment syndrome requiring fasciotomy is not established; and when it is possible to monitor progress and response to treatment (Mathieu et al., 2017).

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS states that 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 4 to 6 hours of the injury, is recommended. The UHMS also recommends HBOT for skeletal muscle compartment syndrome and acute traumatic ischemia (UHMS, 2019). The UHMS updated manual for HBOT indications continues to recommend HBOT for acute traumatic ischemias (UHMS, 2023).

Air Embolism or Gas Embolism

Fakkert et al. (2025) conducted a prospective, single-center, observational cohort study evaluating 6-month functional outcomes and quality of life (QOL) in participants with iatrogenic cerebral air embolism (CAE) treated with HBOT. The cohort included adults diagnosed with CAE between 2020 and 2023 who were able to communicate in Dutch. Clinical characteristics, severity scores, and treatment details were recorded, and primary outcomes included Glasgow Outcome Scale scores at discharge and at 6 months as well as QOL assessments using the World Health Organization QOL brief version at 6 months. All participants received supportive care, and HBOT was initiated promptly, beginning with a U.S. Navy Treatment Table Six protocol followed by daily sessions at 2.4 to 2.5 atmosphere absolute (ATA) for up to 10 treatments, depending on clinical response. Of the 22 participants enrolled, most had arterial CAE, with a median time to HBOT of 7 hours. Mortality was 23%, while eight participants achieved full recovery, and six had moderate disability at 6 months. Over half of survivors reported reduced QOL compared with preincident status. Outcomes appeared more favorable in retrograde venous CAE and poorer in CAE related to neuroangiographic procedures. The study was limited by its single-center design, small sample size, and self-reported QOL measures.

Fakkert et al. (2023) conducted a systematic review and meta-analysis of observational studies to examine whether the timing of HBOT influences outcomes in individuals with iatrogenic cerebral arterial gas embolism. Studies were included if they were in English, involved a cohort of those with iatrogenic cerebral arterial gas embolism included in a defined period of time (excluding case reports/series), and reported both time to HBOT and clinical outcomes at either the group or individual level. In a group-level meta-analysis involving 10 studies and 263 individuals, those with favorable outcomes received HBOT an average of 2.4 hours earlier (95% CI, 0.6-9.7 hours) than those with unfavorable outcomes. A generalized linear mixed-effects model using eight studies and including 126 individuals demonstrated a significant association between shorter time to HBOT and a higher likelihood of a favorable outcome ($p = 0.013$), which remained significant after correcting for severity of manifestations ($p = 0.041$). The probability of a favorable outcome declined from approximately 65% with immediate HBOT to 30% when treatment was delayed 15 hours. The authors concluded that longer delays before HBOT significantly reduce the chance of favorable outcomes, underscoring the critical importance of initiating HBOT as early as possible in cases of iatrogenic cerebral arterial gas embolism. The primary limitations of this review stem from its reliance on observational evidence and the relatively small sample sizes of the included studies.

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

The ECHM recommends HBOT in the treatment of gas embolism and arterial and venous gas embolism with neurological and/or cardiac manifestations. Even if a short interval (less than 6 hours) between embolism and hyperbaric treatment is associated with a better outcome, the 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 et al., 2017).

Undersea and Hyperbaric Medical Society (UHMS)

The 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)

The UHMS states that HBOT should be considered in severe anemia when patients cannot receive blood products for medical, religious, or strong personal preferential reasons or due to 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 continues to recommend HBOT for severe anemia (UHMS, 2023).

Avascular Necrosis (Aseptic Osteonecrosis)

Bozkurt et al. (2022) investigated whether combining HBOT with core decompression provides superior clinical and QOL outcomes compared with HBOT alone. The study included 63 consecutive individuals (80 hips) with Ficat stage II osteonecrosis of the femoral head who were treated between 2012 and 2014 at two independent clinics. Clinic A applied HBOT alone, while clinic B applied combined core decompression and HBOT for all stage II cases. Individuals in the HBOT and core decompression plus HBOT groups had comparable mean ages of approximately 40 years, and follow-up durations averaged around 40 to 43 months. Eligible individuals were adults over 18 years of age with stage IIa or IIb hip osteonecrosis, confirmed by radiographs and magnetic resonance imaging, due to idiopathic, steroid-induced, trauma-related, systemic lupus erythematosus–related, sickle cell–related, or alcohol-related causes. Exclusion criteria included age under 18 years; Ficat stages I, III, or IV; and contraindications to HBOT. Outcomes were evaluated using the modified Harris Hip Score, visual analog scale, and 36-Item Short Form Survey QOL questionnaire. Most hips were classified as Ficat stage IIa (65%), with the remaining 35% categorized as IIb. Of the total sample, 46 hips received HBOT alone, and 34 received combined core decompression plus HBOT. Both groups had significant improvements in visual analog scale and Harris Hip Score ($p < 0.001$), but the gains were notably greater in the combined-therapy group ($p < 0.001$). Additionally, 36-Item Short Form Survey Physical Function and Pain scores differed between groups ($p < 0.005$). The authors concluded that HBOT reduces pain and improves functional outcomes in those with Ficat stage II osteonecrosis. They reported that combining HBOT with core decompression provides even greater clinical benefit than HBOT alone, with particularly notable pain reduction in stage IIa cases. The authors also emphasized the need for larger RCTs to further validate these findings. Limitations include the relatively small sample size and short follow-up period.

Moghamis et al. (2021) conducted a retrospective cohort study to compare the outcomes of core decompression vs. those of HBOT in stage II nontraumatic avascular necrosis (AVN) of the femoral head. Overall, 19 patients, with 23 nontraumatic stage II AVN of the femoral head confirmed by magnetic resonance imaging, were included in the study, with 11 in the HBOT group and 12 in the core decompression group. In total, 66.7% of patients in the core decompression group and 81.8% in the HBOT group achieved a satisfactory hip function outcome, with a statistically significant mean Oxford Hip Score (35.8 ±6.7 and 35.5 ±5.1; $p = 0.009$ and $p = 0.003$, respectively). However, when comparing the two groups directly, there were no statistical differences in the Oxford Hip Score and 12-Item Short Form Survey Physical and Mental Component Summary scores ($p = 0.202$, 0.128, and 0.670, respectively). Eight cases (34.7%) progressed to a higher radiological stage at the 1-year follow-up. The rate of progression was not statistically significant between both groups ($p = 0.469$), with no statistical difference in Oxford Hip Score and 12-Item Short Form Survey (Physical Component Summary and Mental Component Summary) in the progressed group ($p = 0.747$, 0.648, and 0.416, respectively). The authors concluded that in the treatment of nontraumatic, precollapsed AVN of the femoral head, HBOT is as effective as core decompression and could be used as an alternative, noninvasive treatment option. Limitations include the small sample size and 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 that aimed to clarify the clinical effects of HBOT in treating femoral head necrosis (FHN). Ten cohort studies that were 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, and physical and mental relief) and specific improvement in magnetic resonance imaging were evaluated in the studies. The clinical effect in the HBOT group was 3.84 times higher than that 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 individuals (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; future RCTs, with larger sample sizes, 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 that HBOT should be part of a multidisciplinary plan and should not be 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 precollapse stage of articulation (Ficat III, early stage) (UHMS, 2023).

Carbon Monoxide Poisoning

Fujita et al. (2026) conducted a systematic review and meta-analysis to evaluate the effectiveness of HBOT for adults with acute carbon monoxide (CO) poisoning. The review included only RCTs, excluding conference abstracts, animal studies, and any research lacking adequate outcome data. Six trials met the inclusion criteria. Overall, HBOT did not demonstrate a significant reduction in mortality or improvement in neurological outcomes compared with control treatments. A subgroup analysis focusing on treatment pressures of 2.5 ATA or higher also showed no significant benefit. The included studies displayed moderate to substantial heterogeneity, and the quality of evidence was rated as low to very low. The authors concluded that the efficacy of HBOT, even at pressures of ≥ 2.5 ATA, remains uncertain based on the available evidence. Despite the lack of demonstrated benefit in the analyzed trials, the authors noted that HBOT may still offer potential advantages that warrant further investigation. To better clarify its role in the management of CO poisoning, high-quality, multicenter RCTs are needed. Limitations of the review include the small number of eligible RCTs; generally low methodological quality of many included studies, several of which were conducted before current research standards were established; and substantial variability in study designs and treatment protocols.

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 that individuals treated with HBOT have a lower incidence of neuropsychological sequelae than individuals with CO poisoning treated with NBO. Limitations include the small sample sizes in the included studies.

In a Cochrane review, Buckley et al. (2011) evaluated RCTs of HBOT compared with NBO therapy that involved adults who were acutely poisoned with CO. Six RCTs of varying quality were identified, involving 1,361 individuals; two of the trials found a beneficial effect of HBOT for the reduction of neurological sequelae at 1 month, while four others did not. The authors concluded that existing randomized trials do not establish whether the administration of HBOT in individuals with CO poisoning reduces the incidence of adverse neurological outcomes. The authors stated that the results should be interpreted cautiously due to the significant methodological 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 ε4 allele. The apolipoprotein ε4 allele predicts unfavorable neurological outcome after brain injury and stroke. Because the apolipoprotein genotype is unknown at the time of poisoning, the investigators recommended that individuals with acute CO poisoning receive HBOT.

Clinical Practice Guidelines

American College of Emergency Physicians (ACEP)

An updated clinical policy on the 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 neurological outcomes (Shih et al., 2025).

European Committee for Hyperbaric Medicine (ECHM)

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

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS states that 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). The UHMS updated manual for HBOT indications continues to recommend HBOT for CO poisoning (UHMS, 2023).

Central Retinal Artery Occlusion

Elfil et al. (2025) conducted a systematic review and meta-analysis to assess the efficacy and safety of HBOT in the management of retinal artery occlusion. The review included clinical trials and observational studies that directly compared outcomes between individuals treated with HBOT and those receiving standard care, while excluding reviews, editorials, abstracts, and single-arm HBOT studies. Nine studies met the inclusion criteria, encompassing 286 individuals in the HBOT group and 213 in the non-HBOT group, with mean ages ranging from approximately 62.5 to 73.67 years and 60 to 78.5 years, respectively. After sensitivity analysis, HBOT was associated with significant improvement in best-corrected visual acuity (VA; mean difference, -0.63; 95% CI, -1.14 to -0.12; p = 0.01), although no significant differences were found in uncorrected VA or number of lines gained. Reported adverse events in the HBOT group included seizures (1.47%), ear barotrauma (1.65%), and epistaxis (0.83%). Additionally, HBOT was linked to lower rates of neovascular glaucoma (7.89% vs. 15.79%) and stroke (4.3% vs. 16.6%) compared with controls. The authors concluded that HBOT may offer meaningful visual benefits and exhibits an acceptable safety profile in retinal artery occlusion, although variability across studies and limited sample sizes underscore the need for larger, well-designed, prospective trials.

Wu et al. (2018) conducted a meta-analysis to determine the effectiveness of oxygen therapy in individuals with retinal artery occlusion. The primary end point was VA. Seven RCTs met the inclusion criteria. Individuals who received oxygen therapy had a probability of visual improvement approximately 5.61 times compared with the control group, which did not receive oxygen therapy. No statistically significant difference was observed between oxygen inhalation methods, combined therapy, or retinal artery occlusion type. Conversely, 100% oxygen and hyperbaric oxygen significantly improved VA in individuals with retinal artery occlusion. A better effect was shown in a period within 3 months, and the most effective treatment length was over 9 hours. The authors concluded that oxygen therapy had beneficial effects in improving VA in individuals with retinal artery occlusion, especially when they were treated with 100% hyperbaric oxygen for over 9 hours.

Clinical Practice Guidelines

American Academy of Ophthalmology (AAO)

The AAO states that the current evidence for effective interventional treatment for central retinal artery occlusion is controversial; however, the use of HBOT (100% oxygen over 9 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 the application of HBOT as soon as possible in patients with central retinal artery occlusion (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 that a wide variety of treatment modalities has been tried over the last 100 years, with little to no success, except for HBOT. The UHMS recommends that patients presenting within 24 hours of symptom onset should be considered for HBOT and that 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 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 continues to recommend HBOT for central retinal artery occlusion (UHMS, 2023).

Chronic Osteomyelitis

Savvidou et al. (2018) conducted a systematic review assessing the effectiveness and complications of HBOT as an adjunct treatment for chronic osteomyelitis. The inclusion criteria for human studies were met by 14 retrospective and six prospective cohort studies, along with 20 case reports, representing a total of 460 individuals, all of whom had previously

received antibiotics and undergone surgical debridement. Most studies reported mixed bacterial infections, with *Staphylococcus aureus* identified in 60% of cohort studies and 20% of case studies. HBOT demonstrated high effectiveness, with favorable outcomes in 80% of cohort studies and 95% of case studies; overall, 73.5% of individuals with complete data achieved successful, relapse-free results. The authors concluded that HBOT appears to be a safe and potentially valuable adjunct in the management of chronic osteomyelitis. When used alongside standard treatments such as antibiotics and surgical debridement, it has been associated with high recovery rates, particularly when followed by stable bone fixation and removal of infected implants. Although the existing evidence is limited in quality, the authors noted that their review supports HBOT as a potentially beneficial adjunct, especially for cases of refractory chronic osteomyelitis. The review was limited by substantial heterogeneity across studies, inconsistent reporting, and reliance on small, low-quality case reports. Many data were drawn from pre-2000 research, limiting insight into current treatment practices.

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 reported equivocal findings. With data reported in all 15 abstracts included, the median remission rate (defined most consistently as resolution of drainage) was 89% of individuals (range, 37%-100%) for a follow-up as long as 63 months, among 309 individuals reported over 15 studies. On full review, five studies rated a moderate strength of evidence, six were rated as low, and four were rated as 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 patients with chronic refractory osteomyelitis of the femur who were treated with adjunctive HBOT. 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 that HBOT be used in the treatment of refractory osteomyelitis. Additionally, HBOT treatments should last at least 11 to 12 weeks, with approximately 60 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)

The 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). The UHMS updated manual for HBOT indications continues to recommend HBOT for refractory osteomyelitis (UHMS, 2023).

Clostridial Myonecrosis (Gas Gangrene)

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

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

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS states that 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

Uniyal et al. (2025) conducted an RCT evaluating whether HBOT improves split-thickness skin graft uptake in posttraumatic wounds and enhances donor site healing. After randomization, participants were assigned to either standard postoperative care or standard care plus HBOT. The primary outcome was graft uptake, with donor site healing as a secondary measure. Standard care consisted of nonadherent dressings, limb elevation and immobilization, and routine antibiotics and analgesics. The HBOT group received daily sessions at 1.5 to 2 ATA for 90 minutes, beginning on postoperative day 2. Both groups received antibiotics and analgesics, as outlined by institutional protocol, without variation based on treatment group. Participants were adults aged 18 to 60 years undergoing split-thickness skin grafting for traumatic wounds. The exclusion criteria encompassed grafting for nontraumatic wounds, polytrauma, and any

contraindications to HBOT, including pneumothorax, tympanic membrane perforation, claustrophobia, pneumocephalus, or markedly reduced ejection fraction. In total, 64 participants met the eligibility criteria and were enrolled in the study. The HBOT group had higher mean graft uptake than controls on postoperative day 4 (92.44% vs. 88.12%; p = 0.036) and postoperative 7 (91.69% vs. 83.12%; p = 0.026). Donor site healing was also significantly faster with HBOT, averaging 15.16 days compared with 17.97 days in the control group (p < 0.001). In the control group, complications included floating grafts in two participants, flap necrosis in four, and one death from sepsis. In the HBOT group, complications were limited to one case of graft contracture and one wound infection. The authors concluded that HBOT significantly enhanced graft uptake in posttraumatic wounds and promoted faster donor site healing than standard care alone. The authors acknowledged several limitations, including the study's relatively small sample size and the use of acetate tracing to quantify graft uptake, an approach that can be time consuming and may lack precision. An additional limitation is the single-center study design.

ECRI (2023) developed an assessment of HBOT for compromised skin grafts and flap salvage that reports that 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 the outcomes of HBOT in patients with mastectomy flap ischemia. Overall, 50 breasts that required HBOT were included in the review. The Skin Ischemia Necrosis score was used to evaluate the severity of the ischemia or necrosis. HBOT was started at a median of 3 days (range, 1-23 days) after surgery and continued for a median of 12 sessions (range, 6-22). The breast Skin Ischemia Necrosis surface area scores (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 reoperation; higher scores, reflecting more severe necrosis of the mastectomy flap, were associated with an increased need for reoperation. In total, 29 breasts (58%) recovered without additional operation. Preoperative radiotherapy and postoperative infection were risk factors for reoperation in multivariate analyses. The authors concluded that HBOT decreased the surface area of the breast affected by ischemia. The authors stated that future RCTs are needed to confirm or refute that HBOT improves outcomes in individuals with mastectomy flap ischemia.

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)

The ECHM suggests 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 the ECHM is HBOT at a pressure between 203 and 253 kilopascals for at least 60 minutes per session, repeated two to three times in the first day, then twice per day or once daily until tissues are declared alive or necrotic. HBOT is recommended both prior to and post operation in cases in which there is an increased risk for compromised skin grafts and flaps (Mathieu et al., 2017).

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS recommends HBOT in tissue that is compromised by irradiation, in flap salvage, or in other cases in which there is decreased perfusion or hypoxia. Additionally, criteria for selecting the proper patients who are likely to benefit from adjunctive HBOT and identification of the underlying cause of 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

Anseeuw et al. (2013) developed an expert consensus to guide the emergency management of cyanide poisoning from smoke inhalation, highlighting cyanide as a significant yet difficult-to-recognize contributor to fire-related morbidity and mortality. The consensus recommends rapid removal from the exposure source, initiation of basic life support, and immediate administration of high-flow 100% oxygen, which supports treatment of concurrent CO poisoning and may help restore cyanide-inhibited mitochondrial function. While acknowledging mixed evidence, the experts note that HBOT may offer potential benefit in cyanide poisoning.

Clinical Practice Guidelines

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS indications for HBOT website (2019) states that CO and cyanide poisoning frequently occur simultaneously in patients with smoke inhalation and that 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).

Decompression Sickness

In a Cochrane review, Bennett et al. (2012a) examined the safety and efficacy of both recompression therapy (HBOT) 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 nonsteroidal anti-inflammatory drug (tenoxicam) to routine recompression therapy [at 6 weeks: relative risk (RR), 1.04; 95% CI, 0.90-1.20; 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, 0-1). In the other study, the odds of multiple recompressions were lower with a helium and oxygen (heliox) table compared with an oxygen treatment table (RR, 0.56; 95% CI, 0.31-1.00; p = 0.05). The authors concluded that neither the addition of a nonsteroidal anti-inflammatory drug nor the use of heliox improved the odds of recovery but that it 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.

HBOT 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 that 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

El Hadji et al. (2025) conducted a systematic review that evaluated the effectiveness of HBOT in treating late radiation-induced tissue toxicity among those with a history of head and neck cancer (HNC). Eligible studies included those with HNC who had undergone radiotherapy, subsequently developed late radiation-induced tissue toxicity, and were treated with HBOT; only RCTs, cohort studies, and case series were considered. The exclusion criteria eliminated non-English publications, nonhuman studies, inaccessible articles, abstracts, case reports, and studies involving individuals without prior HNC. Seventeen studies, involving 640 individuals aged 20 to 88 years, met the criteria, comprising six RCTs (one pooling data from two trials), seven cohort studies, and four case series. Across these studies, HBOT was generally reported as a safe and reliable intervention, with 14 of 17 studies demonstrating positive clinical outcomes and significant p values noted in 11 studies, particularly in cases involving osteoradionecrosis and oral health complications. A low incidence of adverse effects was reported across the studies. The authors reported that HBOT appears to have potential benefits for treating late radiation-induced tissue toxicity in those with HNC. The authors noted that more robust, high-quality research is required to better determine the clinical effectiveness and appropriate application of HBOT. Limitations include available evidence that is largely based on low-quality studies; small sample sizes; and variable outcome measures.

Yang et al. (2024) conducted a systematic review and meta-analysis to evaluate the safety and efficacy of HBOT for the treatment of radiation-induced hemorrhagic cystitis (RHC). Fourteen studies, with 556 individuals, 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 nonpelvic areas, individuals with radiation cystitis not treated with HBOT, and non-English studies were excluded. Complete resolution of hematuria was the primary end point. 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 include 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 (1,308 individuals) that reported the effect of HBOT on 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 of five studies, of fibrosis in one of two studies, and of lymphedema of the breast and/or arm in four of seven studies. Skin problems of the breast were significantly reduced in one of two studies, arm and shoulder mobility significantly improved in two of two studies, and breast and arm symptoms were significantly reduced in one study. The authors concluded that although the evidence is limited, HBOT might be useful for reducing symptoms of LRT in individuals with breast cancer. The authors recommended future RCTs that include a combination of individual- and clinician-reported outcomes. Limitations include a lack of a control group in most studies and small sample sizes.

Bennett et al. (2016) conducted a systematic review and meta-analysis of RCTs that compared the effect of HBOT vs. that of no HBOT on late radiation tissue injury (LRTI) healing or prevention. The study comprised 14 trials, with a total of 753 individuals. 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 in individuals with LRTI that affects the 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 the optimum timing and selection of individuals. 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 LRTI, comparing it with treatment regimens that did not include HBOT. Four new studies were added to this update, which included 1,071 individuals. The authors concluded that there is some evidence that suggests that HBOT may improve outcomes in LRTI that affects 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, although there is a risk of temporary short-sightedness due to oxygen exposure and potential eardrum injury during compression. Limitations include the small sample sizes and poor reporting of methods and results.

Hampson et al. (2012) reported the collected outcomes in 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 with 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 in 411 individuals strongly supported the efficacy of hyperbaric oxygen treatment for the six conditions evaluated. According to the authors, the response rates that were 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, posttreatment, 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 HBOT. Four individuals healed before surgery after HBOT alone. Of the 57 individuals who experienced improvement, 41 had experienced failure of previous nonmultimodality therapy for 3 months and 26 for 6 months or more. A total of 43 individuals were eligible for time-to-relapse survival analysis. Healing or improvement lasted for a mean duration of 86.1 months in nonsmokers (n = 20), for 15.8 months in smokers (n = 14), and for 24.2 months in individuals with recurrent cancer (n = 9). 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 QOL of irradiated maxillofacial participants; one group of participants (n = 28) was referred for treatment of osteoradionecrosis, which included debridement of necrotic tissue and perioperative HBOT; the second group (n = 38) was referred for therapy to prevent osteoradionecrosis resulting from dental extraction or intraoral implant placement in an irradiated field. Results in both groups suggested that the combination of HBOT and surgery contributed to 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 patients 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, 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 in the treatment of soft tissue radionecrosis (other than cystitis and proctitis). The ECHM states that 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)

The UHMS states that 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 30 to 60 hyperbaric treatments when the course is conducted, with daily treatments at 2.0 to 2.5 ATA for 90 to 120 minutes (UHMS, 2019). The UHMS updated manual for HBOT indications continues to recommend HBOT for delayed radiation injury (UHMS, 2023).

Diabetic Lower Extremity Wounds

Oley et al. (2024) conducted a systematic review and meta-analysis evaluating the benefits and risks of HBOT compared with those of other treatment modalities for diabetic foot ulcers (DFUs) based on the Wagner grading system. The review included RCTs enrolling adults with type 1 or type 2 diabetes who had lower extremity ulcers that had persisted for at least 30 days, remained unresponsive to standard therapy, and were present with or without underlying vascular insufficiency. Eligible studies applied HBOT at pressures of 2.0 to 3.0 ATA for a minimum of 45 minutes, once or twice daily, in mono- or multiplace chambers; the control groups received the standard wound-healing treatments used at their respective institutions or other non-HBOT therapies. The exclusion criteria were individuals who underwent amputations on the ulcer extremity before the trial and those with chronic ulcers that were not diabetic related. Fifteen trials met the inclusion criteria. HBOT demonstrated significantly greater effectiveness than comparator treatments, showing higher wound-healing rates 8 or more weeks after treatment completion (RR, 2.39; 1.87-3.05; $p < 0.00001$) as well as reductions in both minor/distal amputations (RR, 0.58; 0.43-0.80; $p < 0.007$) and major/proximal amputations (RR, 0.31; 0.18-0.52; $p < 0.00001$) across the 14 studies analyzed. The therapy also substantially improved complete healing for Wagner grades 2 (RR, 21.11; 3.05-146.03; $p = 0.002$), III (RR, 19.58; 2.82-135.94; $p = 0.003$), and IV (RR, 17.53; 2.45-125.44; $p = 0.004$). Additionally, HBOT was associated with lower rates of minor/distal amputation in grade 3 ulcers (RR, 0.06; 0.01-0.29; $p = 0.0004$), reduced major/proximal amputation rates in grade 4 ulcers (RR, 0.08; 0.03-0.25; $p < 0.0001$), and decreased operative debridement requirements for grade 2 wounds (RR, 0.09; 0.01-0.60; $p = 0.01$). The authors concluded that moderate-quality evidence supports adjunctive HBOT as an effective therapy for enhancing wound healing in Wagner grade 2 to 4 DFUs and that adjunctive HBOT reduces minor amputation rates in grade 3 ulcers, reduces major amputation rates in grade 4 ulcers, and decreases the need for operative debridement in grade 2 wounds. The study's limitations include the heterogeneity in HBOT protocols and standard care comparators and small sample sizes in the individual studies.

Tao et al. (2024) performed a systematic review and meta-analysis to evaluate the efficacy and safety of HBOT in the treatment of DFUs. The inclusion criteria for the study included individuals in RCTs who were diagnosed with DFUs and were undergoing HBOT, either as a stand-alone 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 an 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; it also demonstrates commendable safety profiles. Limitations include the small sample sizes of some of the studies; selection bias, in which individuals were not randomly selected; and 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 DFUs, mortality rate, complete healing, adverse events, amputation, and ulcer reduction area. Fourteen studies (768 individuals), including 12 RCTs and two controlled clinical trials, were included. The results with a pooled analysis showed that HBOT was significantly effective in the complete healing of DFUs (OR, 0.29; 95% CI, 0.14-0.61; I^2 = 62%) and reduction of major amputation (RR, 0.60; 95% CI, 0.39-0.92; I^2 = 24%). HBOT was not effective for minor amputations (RR, 0.82; 95% CI, 0.34-1.97; I^2 = 79%); however, less adverse events were reported in the standard treatment group (RR, 1.68; 95% CI, 1.07-2.65; I^2 = 0%). The reduction in the mean percentage of ulcer area and mortality rate did not differ in the HBOT and control groups. The authors concluded that HBOT was associated with lower major amputation rates and higher rates of healed DFUs and that HBOT as an adjunctive treatment measure for the DFU is effective. Limitations include that (1) only six of 14 trials that were included performed sample size calculations and that (2) the duration and techniques used in HBOT while treating individuals were not uniform in most of the studies. The authors recommended that HBOT should be used with caution when treating DFUs, and future multicentric trials to assess the 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. Overall, 20 RCTs met the inclusion criteria and were included in the study. HBOT increased the healing rate of DFUs (RR, 1.901; 95% CI, 1.484-2.435; $p < 0.0001$), shortened the healing time (mean difference, -19.360; 95% CI, 28.753 to -9.966; $p < 0.001$), and reduced the incidence of major amputation (RR, 0.518; 95% CI, 0.323-0.830; $p < 0.01$). The authors concluded that HBOT has considerable benefit in healing DFUs and decreasing amputation rate. The authors recommended future RCTs to evaluate the efficacy of HBOT for healing DFUs. Londahl et al. (2011), previously cited in this policy, was included in this study.

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 included HBOT, with that of regimens that excluded HBOT (with or without sham therapy). Twelve trials (577 individuals) were included in the review. Ten trials (531 individuals) enrolled people with a DFU; pooled data from five trials, with 205 individuals, showed an increase in the rate of ulcer healing with HBOT at 6 weeks. However, this benefit was not evident at the longer-term follow-up at 1 year. There was no statistically significant difference in major amputation rate. One trial (16 individuals) considered venous ulcers and reported data at 6 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 6 weeks. One trial (30 individuals) enrolled individuals with nonhealing diabetic ulcers as well as venous ulcers (mixed ulcer types), and individuals were treated for 30 days. For 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 that individuals in whom HBOT significantly improved the ulcers healed in the short term but not the long term. The authors stated that the trials that were reviewed had various flaws and recommended future trials to evaluate HBOT in people with chronic wounds.

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 patients with diabetes and patients with arteriosclerosis is recommended in the presence of a chronic critical ischemia (Mathieu et al., 2017).

International Working Group on the Diabetic Foot (IWGDF)

Chen et al. (2024) developed an IWGDF guideline that states that the use of HBOT as an adjunct therapy in neuroischemic or ischemic diabetes-related foot ulcers, for which standard of care alone has failed and resources already exist to support this intervention, can be considered. Strength of recommendation: conditional; certainty of evidence: low.

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 4 weeks of standard wound therapy, adjunctive wound therapy options, including HBOT, are recommended. In patients with DFUs who have adequate perfusion that fails to respond to 4 to 6 weeks of conservative management, HBOT is suggested (Hingorani et al., 2016).

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS recommends HBOT for patients with Wagner grade 3 or higher DFUs who have not experienced 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 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 continues to recommend HBOT for DFUs (UHMS, 2023).

Idiopathic Sudden Sensorineural Hearing Loss

Moghib et al. (2025) conducted a systematic review and meta-analysis evaluating HBOT as an add-on treatment for sudden sensorineural hearing loss (SSNHL). The study compared outcomes in those receiving HBOT plus systemic corticosteroids with those treated with corticosteroids alone. This review included English-language RCTs of adults diagnosed with SSNHL using the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) criteria. Studies were eligible if they compared HBOT, alone or combined with systemic or intratympanic steroids, with steroid therapy, placebo, or no treatment. Only trials conducted before January 2025 with clearly defined diagnostic criteria were included, and they were required to report outcomes such as hearing improvement, recovery rates, time to improvement, or adverse effects. Fourteen studies were included in the review, for a total of 794 individuals. The results showed that combining HBOT with systemic corticosteroids led to significantly improved low-frequency hearing thresholds and increased the likelihood of complete recovery. Reported adverse effects, such as vertigo, occurred but were generally mild. The authors concluded that adding HBOT to systemic corticosteroids may enhance hearing recovery in idiopathic SSNHL (ISSHL), especially for low-frequency deficits within the first 3 months. The authors emphasized the need for well-designed RCTs, with standardized protocols and clear selection of individuals, along with future studies aimed at identifying those who would benefit most and optimizing treatment regimens. The study's limitations include substantial heterogeneity, lack of standardized protocols for HBOT, and lack of uniform selection of individuals.

Cavaliere et al. (2022) conducted an RCT to compare the effect of HBOT, oral steroids (OSs), and a combination of both therapies (HBOT + OS) for treating SSNHL. Overall, 171 participants with SSNHL were randomized and included in the study. Participants were evaluated by a pure-tone audiometry test at baseline and 20 days after treatment. After a baseline pure-tone audiometry test, participants were randomly assigned to each group: HBOT group A, OS group B, or HBOT + OS group C. Participants in the HBOT + OS and HBOT groups had improved auditory function ($p < 0.05$). HBOT was the best choice for treatment when started by 7 days from SSNHL onset, whereas HBOT + OS was more effective for cases in which treatment was delayed. Profound SSNHL recovered equally with HBOT and HBOT + OS ($p < 0.05$). Upsloping SSNHL obtained better auditory results with HBOT than HBOT + OS ($p < 0.05$). Downsloping and flat SSNHL had the most improvement with HBOT + OS compared with 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 the 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 used as a single treatment or part of the combination regimen. The study included three RCTs, which included 88 individuals who received HBOT in intervention groups and 62 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; $I^2 = 0\%$) and the OR of hearing recovery (4.3; 95% CI, 1.6-11.7; $I^2 = 0\%$) favored HBOT over the control therapy. The authors suggested that HBOT, as part of a combination treatment regimen, should be considered for individuals with SSNHL. Limitations include the small sample sizes of the studies; additionally, 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 a 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 2,401 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 1,200 minutes. The authors concluded that particularly, in 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 that further trials that use well-defined indications and standardized protocols of HBOT are warranted.

Bennett et al. (2012b) updated a Cochrane review, which was 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 individuals) that compared the effect of HBOT and alternative therapies on tinnitus and ISSHL were included. Pooled data from the 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 (6 months) of ISSHL and/or tinnitus. The authors concluded that the application of HBOT significantly improved hearing in people with acute ISSHL but that the clinical significance remained unclear. The authors noted that 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 2 weeks of onset of SSNHL. Additionally, HBOT was recommended when combined with steroid therapy as salvage within 1 month of onset of SSNHL (Chandrasekhar et al., 2019).

European Committee for Hyperbaric Medicine (ECHM)

The ECHM recommends HBOT in the treatment of acute ISSHL combined with medical therapy in patients who present within 2 weeks of disease onset. Additionally, the ECHM states that it would be reasonable to use HBOT as an adjunct to corticosteroids in patients presenting after the first 2 weeks but not later than 1 month, especially in those with severe and profound hearing loss (Mathieu et al., 2017).

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS includes SSNHL as a recommended indication for HBOT in 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; the best evidence supports the use of HBOT within 2 weeks of symptom onset (UHMS, 2019). The UHMS updated manual for HBOT indications continues to recommend HBOT for ISSHL (UHMS, 2023).

Intracranial Abscess

Brunner et al. (2025) conducted a retrospective study comparing outcomes in adults with brain abscesses who received standard therapy alone vs those in patients who also received adjunctive HBOT. Of 63 patients treated between 2004 and 2022, 55 met the inclusion criteria after excluding those younger than 18 years and those with incomplete data. All patients received conventional management, such as antimicrobial treatment, source control, and surgery, when indicated. Use of adjuvant HBOT was determined case by case through interdisciplinary review based on the patient's overall clinical status. Follow-ups occurred at 3, 6, and 12 months after initial diagnosis. Overall, 30 patients (54.5%) received standard care only, while 25 (45.5%) also underwent HBOT. At 3 months, 24% of patients in the HBOT group and 10% in the non-HBOT group had no remaining abscess or abnormal enhancement. By 6 months, 80% of the HBOT group had resolution compared with 46.7% of the standard therapy group (p = 0.009). At 12 months, 60% of those who received HBOT were symptom free (modified Rankin Scale 0) vs. 30% of controls (p = 0.046). Mortality at 12 months was lower in the HBOT group (12%) than in the non-HBOT group (20%), and no HBOT-related adverse effects were reported. The authors concluded that adjuvant HBOT improved radiological outcomes at 6 months, enhanced neurological recovery by 12 months, and reduced mortality. The authors recommended considering HBOT for all individuals with brain abscesses, particularly those with deep-seated or multiple lesions or those who respond poorly to antimicrobial or surgical therapy. Study limitations include its retrospective, single-center design; small sample size; and nonstandardized follow-up.

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. Overall, 20 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 26 individuals who did not receive HBOT after the first surgery, 15 (58%) had one or several recurrences that led to a new treatment: surgery (n = 11), surgery + HBOT (n = 5), or just HBOT (n = 1). In contrast, recurrences occurred in only two of 14 (14%) who did receive HBOT after the first surgery. A good outcome

(Glasgow Outcome Scale score of 5) was achieved in 16 individuals (80%) in the HBOT cohort vs nine individuals (45%) in the non-HBOT group. The authors concluded that HBOT was well tolerated and safe, was associated with less treatment failures and need for reoperation, and appeared to have improved long-term outcomes. The authors stated that 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 HBOT on the duration of antibiotic treatment. The study included 13 individuals (mean age, 43.9 years) with bacterial brain abscesses treated with stereotactic aspiration combined with HBOT and systemic antibiotic therapy. Post operation, all individuals were given a 4-week course of intravenous antibiotics. Additionally, individuals received hyperbaric oxygen (100% oxygen at 2.5 ATA for 60 minutes) twice daily for 5 consecutive days, and an additional treatment (100% oxygen at 2.5 ATA for 60 minutes 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 a 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 were without sequelae, and three had mild hemiparesis but were capable of self-care. One individual had moderate hemiparesis. The authors stated that although the number of individuals is small, the series represented the largest reported group of individuals with brain abscesses treated with stereotactic aspiration combined with antibiotics and HBOT. 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 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 intracranial 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)

The UHMS recommends adjunct HBOT for intracranial abscess in patients with multiple abscesses, abscesses in a deep or dominant location, or a compromised host; in situations in which surgery is contraindicated or a poor surgical risk is present; and when there is no response or further deterioration in spite of standard surgical and antibiotic treatment. Per the 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 continues to recommend HBOT for intracranial abscess (UHMS, 2023).

Necrotizing Infections

Patel and Batura (2026) conducted a systematic review and meta-analysis to evaluate how HBOT affects outcomes in adults diagnosed with Fournier gangrene. English-language studies published within the last 20 years that examined individuals aged 18 years or older and compared standard treatment alone with standard treatment plus HBOT were included. Studies were required to report mortality, while hospital length of stay and the number of surgical debridements were included as secondary outcomes. The authors excluded studies focused on other types of necrotizing infections as well as conference abstracts, reviews, editorials, animal studies, single case reports, and case series with fewer than five individuals. Studies that did not provide data relevant to assessing the effectiveness of HBOT were also excluded. The review included 13 retrospective studies, which involved 322 individuals who received HBOT and 366 individuals in the control groups. HBOT was linked to a significantly lower mortality rate compared with standard care alone. However, secondary outcomes, such as hospital length of stay and the number of surgical debridements, varied across studies and did not show meaningful differences between the groups. The findings led the authors to conclude that HBOT has the potential to decrease mortality in Fournier gangrene and may serve as a valuable adjunctive treatment option. Several limitations were identified, including the retrospective design of the studies and their relatively small sample sizes.

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 (NSTIs). A total of 23 retrospective cohort and case-control studies met the inclusion criteria, including 1,448 individuals who received HBOT and 47,704 in the control. The mortality rate was the primary outcome. The 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 that in the non-HBOT group (standardized mean difference, 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 multiple organ dysfunction syndrome 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 that the use of HBOT significantly reduced the mortality rates and incidence rates of complications in the treatment of NSTI. Limitations include the varied duration and frequency of HBOT across the studies and retrospective nature of the studies. The authors recommended further research to establish efficacy.

Hedetoft et al. (2021) conducted a systematic review and meta-analysis of the evidence to support or refute the use of HBOT in the treatment of NSTI. The primary outcome was in-hospital mortality. Overall, 31 studies were included in the qualitative synthesis, with 21 in the meta-analyses. A meta-analysis in 48,744 individuals with NSTI [1,237 (2.5%) HBOT vs. 47,507 (97.5%) non-HBOT] showed that in-hospital mortality was 4,770 of 48,744 individuals overall (9.8%); the pooled OR was 0.44 (95% CI, 0.33-0.58) and in favor of HBOT. For major amputation, the pooled OR was 0.60 (95% CI, 0.28-1.28) and in favor of HBOT. The dose of oxygen in these studies was incompletely reported. The authors concluded that individuals with NSTI treated with HBOT may be less likely to require a major amputation and have reduced odds of dying during a sentinel event. Additionally, the authors noted that 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 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 the treatment of NF. The selection criteria included all randomized and pseudorandomized trials that compared the effects of HBOT with the effects of no HBOT in NF. No trials were found that met the 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)

The UHMS recommends HBOT for NF, stating that 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 continues 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 the management of skin and soft tissue infections states that although the benefit of adjuvant HBOT remains controversial, it may be considered when 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 that HBOT for the treatment of second-degree burns greater than 20% body surface area and burns to the face, neck, hands, or perineum may provide benefit, even if the total surface burned is less than 20%. Furthermore, the ECHM recommends that only specialized HBOT centers in the immediate vicinity of a burn center treat burns as an adjunct to classical burn care (Mathieu et al., 2017).

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS states that HBOT for burns is recommended in patients with a burn that is 20% or greater total body surface area and/or that affects the 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 that adjunctive HBOT is recommended, as it can benefit each of these problems directly (UHMS, 2019). The UHMS updated manual for HBOT indications continues to recommend HBOT for thermal burn injuries (UHMS, 2023).

Other Indications

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

Mild Hyperbaric Oxygen Therapy

Conclusions on the benefit of mild HBOT (mHBOT) are derived from animal studies; small, uncontrolled studies; and 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 a 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 for the treatment of acute mountain sickness.

Clinical Practice Guidelines

European Committee for Hyperbaric Medicine (ECHM)/European Underwater and Baromedical Society (EUBS)

The 2022 ECHM-EUBS joint position statement on mild hyperbaric therapy strongly advises against the use of pressure chambers that fail to comply with the European Union Medical Devices Regulation or are not approved under the ECHM, European Diving Technology Committee, or European Baromedical Association standards. The organizations do not endorse mild hyperbaric therapy outside approved safety guidelines and indications and caution against promoting these devices for wellness or therapeutic claims that lack scientific evidence.

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 of less than 1.4 ATA while the patient breathes 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

Quality evidence in peer-reviewed, medical literature that evaluated topical oxygen therapy (TOT) is limited. Future robust RCTs are warranted, along with long-term outcomes, to establish the safety and efficacy of this treatment.

Zhu et al. (2026) conducted a two-arm RCT evaluating the efficacy and safety of a portable continuous diffusion of oxygen (CDO) TOT system vs. those of moist wound therapy in adults with chronic wounds. The study enrolled participants aged ≥ 18 years who had wounds persisting for > 4 weeks and measuring 2 to 25 cm^2 and ≥ 0.5 cm deep; could adhere to treatment; and had no dressing sensitivities. The exclusion criteria included secondary osteomyelitis or malignant wounds; active bleeding; wounds in locations difficult to seal; severe systemic illness impairing healing; use of immunosuppressive, steroidal, or chemotherapeutic agents; or participation in another clinical trial within the past 3 months. The study's primary outcomes were the percentage reduction in wound area at day 28 and the wound healing rate at both day 28 and week 12. Overall, 88 participants were randomized to receive either TOT (n = 44) or moist wound therapy (n = 44) for a 28-day treatment period, with any unhealed wounds subsequently managed using standardized moist wound therapy through week 12. Weekly assessments measured wound area, depth, pH, healing rate, healing time, and adverse events. By day 28, TOT produced significantly greater reductions in wound area and depth and resulted in lower wound bed pH than moist wound therapy. The TOT group had a substantially higher healing rate at day 28 (45.5% vs. 11.4%), but by week 12, both groups reached similarly high healing rates (95.5% vs. 90.9%; p = 0.536). The overall healing time was shorter with TOT by an average of 13.5 days, and no TOT-related adverse events were observed. The authors concluded that portable TOT markedly accelerates healing in chronic wounds, with reductions in wound bed pH contributing to improved conditions that promote subsequent tissue repair processes. The study's limitations include its single-center design and modest sample size; heterogeneity of wound types and comorbidities that prevented subgroup analyses, especially for DFUs and venous leg ulcers; and a short 12-week follow-up period that limited assessment of long-term healing and recurrence.

A 2025 Hayes Evolving Evidence Review indicated that continuous TOT appears reasonably safe as an adjunctive treatment for DFUs, with most reported adverse events being mild to moderate and only a small proportion considered possibly or probably related to the device. The addition of continuous TOT to conventional wound therapy was not associated with an increased risk of adverse events. Evidence from full-text clinical studies and systematic reviews provides moderate support for continuous TOT as an adjunct to standard care in the management of chronic DFUs, although clinical practice guidelines and professional position statements offer only weak endorsement. Overall, while

safety data are reassuring and the existing evidence suggests potential benefit, stronger and more consistent guideline support will likely require additional high-quality studies.

OuYang et al. (2024) conducted a network meta-analysis comparing various treatment strategies for DFUs and assessing their effects on ulcer healing. The analysis included 57 RCTs, involving 4,826 individuals. The study found that TOT improved complete ulcer healing rates compared with standard of care in both direct and network meta-analyses. However, TOT did not show a measurable advantage over other treatments in reducing ulcer area or shortening healing time, which were benefits that were primarily associated with platelet-rich plasma and negative pressure wound therapy. In terms of safety outcomes, including amputation rates and adverse events, TOT did not differ significantly from other interventions. Although TOT outperformed the standard of care, it did not rank among the most effective treatments in the network analysis, in which combination therapies involving platelet-rich plasma and negative pressure wound therapy demonstrated the highest overall performance across healing, size reduction, healing time, and safety outcomes. According to the authors, DFU treatment often works best when multiple therapies are combined. Clinicians can tailor single or combined treatments, based on the ulcer's characteristics, and weigh the benefits and risks for each individual. The authors suggested that more clinical trials are needed to further evaluate the effectiveness of combination therapies for DFUs. The study's limitations include variability in individuals' demographics, inconsistent measurement timing across studies, and lack of blinding.

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 that 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 showed 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 noted 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 include the short follow-up periods and small sample sizes in some of the studies. Tawfick and Sultan (2009) and Blackman et al. (2010), 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, off-loading, and moist wound care) for Wagner 1 and 2 DFUs. The primary outcome of interest was complete wound healing at 12 weeks, and the secondary outcomes were wound-related pain, hospital readmissions, QOL, adverse effects, dependence on 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. The pooled results showed statistical significance, with an RR of 1.59 (95% CI, 1.07-2.37; p = 0.021). A sensitivity analysis, based on imputed values for missing outcomes, demonstrated that both the RR and 95% CIs changed little. The GRADE (Grading of Recommendations Assessment, Development, and Evaluation) ratings for each domain were moderate (3) for risk of bias; moderate (2) and high (1) for imprecision; low (2) and high (1) for inconsistency; moderate (2) and high (1) for indirectness; and moderate (1) and high (2) for publication bias. 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 include the short-term follow-up and small study size; additionally, the confidence in the authors' conclusions may be limited by their stated financial conflicts of interest.

Sun et al. conducted a 2022 systematic review and meta-analysis evaluating the efficacy and safety of TOT for DFUs, ultimately including seven studies that involved 614 individuals. Eligible studies were those that enrolled individuals with DFUs who were using TOT either alone or alongside standard care, comparing with standard care controls and reporting outcomes such as ulcer healing, ulcer area, healing time, adverse events, follow-up, or QOL measures; studies that lacked essential data, abstracts only, duplicate interim reports, and trial protocols were excluded. The included studies, most involving continuous diffusion oxygen therapy and others evaluating intermittent TOT, consistently showed that TOT improved healing outcomes, with a higher healing rate (RR, 1.63; 95% CI, 1.33-2.00) and qualitative evidence of reduced ulcer area, greater healing durability, and enhanced QOL, without an increase in adverse events; however, its effect on healing time remained uncertain. The authors concluded that existing evidence supports TOT as an effective and safe option for DFUs, although further high-quality research is needed to clarify mechanisms and optimize treatment strategies. Limitations include inconsistent eligibility criteria, variable interventions and treatment durations, heterogeneity in care delivery settings, insufficient data for comparing continuous vs intermittent TOT, and a lack of additional double-blinded, placebo-controlled trials.

An ECRI Clinical Evidence Assessment (2021) that evaluated the safety and efficacy of TOT for treating DFUs compared with those of 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. In the updated 2025 ECRI summary, evidence from three systematic reviews showed that adding TOT to standard care improves DFU healing compared with standard care alone. One network meta-analysis suggested that TOT may be less effective than platelet-rich plasma, stem cells, or platelet-rich plasma combined with negative pressure wound therapy; however, more high-quality, head-to-head studies are needed to confirm this. Additional RCTs are also needed to identify the optimal TOT application method and to directly compare TOT with other therapies.

He et al. (2021) conducted a single-center RCT to determine the effect of CDO combined with traditional moist wound dressing (MWD) on the DFUs of inpatients. Participants were randomly divided into three groups that consisted of 40 participants 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. The amputation rate, wound healing, and inflammatory control were evaluated after 8 weeks of treatment. Compared with the MWD and CDO groups, the combination group had 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 the 1-year follow-up, the amputation rate was 0% in the combination group, which was significantly lower than that in the other two groups ($p < 0.05$). The authors concluded that 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 recommended larger, randomized, double-blinded studies in the future.

Clinical Practice Guidelines

International Working Group on the Diabetic Foot (IWGDF)

Chen et al. (2024) developed an IWGDF guideline that states that the use of TOT as an adjunct therapy to standard of care for wound healing in people with diabetes-related foot ulcers, for which standard of care alone has failed and resources exist to support this intervention, may be considered. Strength of recommendation: conditional; certainty of evidence: low.

National Institute for Health and Care Excellence (NICE)

NICE (2020) performed an innovation briefing that states that 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, nonhealing 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 shows that the NATROX device had an effect, the small sample sizes and heterogeneous populations involved reduced the overall significance of the findings.

Undersea and Hyperbaric Medical Society (UHMS)

The UHMS states that application of topical oxygen cannot be recommended in 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 a therapy for nonhealing 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 website for more information, and use product code CBF (hyperbaric chamber): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 27, 2026)

Adverse events with hyperbaric chambers are reported in the FDA Manufacturer and User Facility Device Experience database. For information on adverse events reported with 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 January 27, 2026)

Hyperbaric semirigid chambers for low pressures (operating at pressures of 1.3-1.5 atmosphere absolute) 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 January 27, 2026)

Note: The American Medical Association released a Legislation and Regulation statement in 2022 that notes 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 American Medical Association states that they would collaborate with the FDA 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 January 27, 2026)

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 website for more information (use product code KPJ): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 27, 2026)

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Policy History/Revision Information

Date	Summary of Changes
05/01/2026	**Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version 2026T0632I

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, 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).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.