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MEDICAL POLICY – 2.01.505

Hyperbaric Oxygen Therapy

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Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

Hyperbaric oxygen therapy is a way to treat some medical conditions by delivering pure oxygen to a person at a higher-than-normal pressure. There are two ways to do this: systemic hyperbaric oxygen therapy and topical hyperbaric oxygen therapy.

In systemic hyperbaric oxygen therapy, a person is put in a sealed chamber and breathes pure oxygen that is under increased pressure. The lungs are thus able to collect more oxygen than would otherwise be possible at normal air pressure. The blood then carries the oxygen throughout the body to stimulate healing. Systemic hyperbaric oxygen therapy is a proven treatment in certain situations to treat serious infections, wounds that will not heal, or to clear dangerous bubbles or gasses in the blood, like when a person has “the bends.”

Topical hyperbaric therapy has been used to help an open wound heal. It involves placing a sleeve or other device around the limb that has the wound on it. The sleeve is then sealed in place, and higher than normal oxygen pressure is applied to the wound. This type of hyperbaric treatment is investigational (unproven). There is not enough scientific evidence to show that topical hyperbaric oxygen therapy leads to improved health results.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a

service may be covered.

Policy Coverage Criteria

Therapy	Medical Necessity

Systemic hyperbaric oxygen pressurization therapy	**Systemic hyperbaric oxygen pressurization therapy may be considered medically necessary in the treatment of the following conditions:**
	• Acute traumatic ischemia (e.g., crush injuries, reperfusion injury, compartment syndrome)
	• Anemia from exceptional blood loss (profound): only when a blood transfusion is impossible or must be delayed
	• Carbon monoxide poisoning, acute
	• Central retinal artery occlusion (CRAO)
	• Compromised skin grafts or flaps
	• Cyanide poisoning, acute
	• Decompression sickness
	• Gas embolism, acute
	• Gas gangrene (i.e., clostridial myonecrosis)
	• Idiopathic sudden sensorineural hearing loss
	• Necrotizing soft tissue infections
	• Non-healing diabetic wounds of the lower extremities in individuals who meet the following 3 criteria:
	  ○ Individual has type 1 or type 2 diabetes and has a lower extremity wound due to diabetes;
	  ○ Individual has a wound classified as Wagner grade 3 or higher (see **Related Information**); and
	  ○ Individual has no measurable signs of healing after 30 days of an adequate course of standard wound therapy (see **Related Information**);
	• Osteomyelitis, chronic refractory
	• Pre-and posttreatment for individuals undergoing dental surgery (non-implant-related) of an irradiated jaw
	• Soft tissue radiation necrosis (e.g., radiation enteritis, cystitis, proctitis) and osteoradionecrosis

Therapy	Investigational
Hyperbaric oxygen pressurization	**Hyperbaric oxygen pressurization is considered investigational in all other situations, including but not limited to, the treatment of the following conditions:** • Acute peripheral arterial insufficiency • Acute coronary syndromes and as an adjunct to coronary interventions, including but not limited to, percutaneous coronary interventions and cardiopulmonary bypass • Acute ischemic stroke • Acute osteomyelitis • Acute surgical and traumatic wounds not meeting criteria specified in the medically necessary statement above • Acute thermal burns • Autism spectrum disorder • Bell's palsy • Bisphosphonate-related osteonecrosis of the jaw • Bone grafts • Brown recluse spider bites • Carbon tetrachloride poisoning, acute • Cerebral edema, acute • Cerebral palsy • Cerebrovascular disease, acute (thrombotic or embolic) or chronic • Chronic arm lymphedema following radiotherapy for cancer • Chronic wounds, other than those in individuals with diabetes who meet the criteria specified in the medically necessary statement above • Delayed-onset muscle soreness • Demyelinating diseases (e.g., multiple sclerosis, amyotrophic lateral sclerosis) • Early treatment (beginning at completion of radiotherapy) to reduce adverse events of radiotherapy • Fibromyalgia; • Fracture healing • Herpes zoster • Hydrogen sulfide poisoning • Idiopathic femoral neck necrosis • In vitro fertilization

Therapy	Investigational
	• Inflammatory bowel disease (Crohn disease or ulcerative colitis) • Intra-abdominal and intracranial abscesses • Lepromatous leprosy • Meningitis • Mental illness (i.e., posttraumatic stress disorder, generalized anxiety disorder, or depression). • Migraine • Motor dysfunction associated with stroke • Pseudomembranous colitis (antimicrobial agent-induced colitis) • Pyoderma gangrenosum • Radiation myelitis • Radiation-induced injury in the head and neck, except as noted earlier in the medically necessary statement above • Refractory mycoses: mucormycosis, actinomycosis, conidiobolus coronato • Retinopathy, adjunct to scleral buckling procedures in individuals with sickle cell peripheral retinopathy and retinal detachment • Sickle cell crisis and/or hematuria • Spinal cord injury • Traumatic brain injury • Tumor sensitization for cancer treatments, including but not limited to, radiotherapy or chemotherapy • Vascular dementia
Topical hyperbaric oxygen therapy	**Topical hyperbaric oxygen therapy is considered investigational.**

Documentation Requirements

The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:
• Diagnosis/condition
• History and physical examination documenting the severity of the condition
• For non-healing diabetic wounds:
  ○ Wagner ulcer grade
  ○ Prior therapy attempted

Coding

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

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Standard Wound Therapy

- Assessment of vascular status; correction of vascular problems in the affected limb if possible
- Optimization of glycemic control
- Optimization of nutritional status
- Topical wound treatment with maintenance of a clean, moist bed of granulation tissue
- Debridement to remove devitalized tissue
- Pressure reduction or off-loading
- Treatment to resolve infection (e.g., antibiotics)

Evidence

There is limited comparative evidence for HBOT. The policy is based on the best available evidence and is largely informed by clinical input and guidelines.

Topical Hyperbaric Oxygen

Healthcare Common Procedural Coding System (HCPCS) code A4575 is used to describe a disposable topical hyperbaric oxygen appliance that creates a "chamber" around the wound area which is pressurized with "hyperbaric oxygen." Conventional oxygen tanks, typically gas, are used to supply the oxygen. An example of such a device is the AOTI Hyper-Box.

This policy addresses topical hyperbaric oxygen therapy (HBOT), but not topical oxygen wound care.

Topical HBOT may be performed in the office, clinic, or may be self-administered by the individual in the home. Typically, the therapy is offered for 90 minutes per day for 4 consecutive days. After a 3-day break, the cycle is repeated. The regimen may last for 8 to 10 weeks.

Systemic Hyperbaric Oxygen

The Wagner Ulcer Grade Classification System

The Wagner classification system categorizes wounds as follows:

Grade	Lesion
0	No open lesion
1	Superficial ulcer without penetration to deeper layers
2	Ulcer penetrates to tendon, bone, or joint
3	Lesion has penetrated deeper than grade 2 and there is abscess, osteomyelitis, pyarthrosis, plantar space abscess, or infection of the tendon and tendon sheaths
4	Wet or dry gangrene in the toes or forefoot
5	Gangrene involves the whole foot or such a large percentage that no local procedures are possible and amputation (at least at the below the knee level) is indicated

Following are recommended indications from the Undersea and Hyperbaric Medical Society's (UHMS) 2023 Hyperbaric Oxygen Therapy Committee report on utilization of HBOT (15th edition):

- Acute thermal burn injury
- Acute traumatic ischemias
- Air or gas embolism
- Arterial insufficiencies: Central retinal artery occlusion; Hyperbaric oxygen therapy for selected problem wounds
- Avascular necrosis (aseptic osteonecrosis) [1]
- Carbon monoxide poisoning and carbon monoxide complicated by cyanide poisoning
- Clostridial myonecrosis (gas gangrene)
- Compromised grafts and flaps
- Decompression sickness
- Delayed radiation injury (soft tissue and bony necrosis)
- Intracranial abscess
- Necrotizing soft tissue infections
- Refractory osteomyelitis
- Severe anemia
- Sudden sensorineural hearing loss

HBOT refers to treatment at pressures greater than 1.4 atmospheres absolute, administered in a hard-sided hyperbaric chamber that meets applicable safety standards. Tissue oxygen tensions greater than 250mmHg are required to halt the alpha toxin production of clostridial infection. This level of tissue oxygen tension can only be achieved with HBOT treatment. (It should be noted that Group A streptococcus produces a toxin similar to the alpha toxin of Clostridium myonecrosis infections.)

Progressive Necrotizing Soft Tissue Infections

Necrotizing soft tissue infection (NSTI) is a set of disorders characterized by a rapidly progressive infection with necrosis or gangrene. No definition of "progressive" was identified. However, definition of NSTI includes progression of infection despite antibiotic therapy. UHMC clinical input speaks to progressive NSTI in terms of NSTI while receiving broad spectrum antibiotics with either performed or planned therapeutic and diagnostic surgical debridement. The UHMC input also notes that frozen section soft-tissue biopsy is the gold standard of diagnosis, but that is not feasible in practice. There are no unique clinical considerations based

on the wound characteristics, site and/or depth of infection or time to treatment. By their very nature, NSTI are life and limb threatening.

Idiopathic Sudden Sensorineural Hearing Loss (ISSHL)

Idiopathic sudden sensorineural hearing loss (ISSHL) is an abrupt loss of hearing, typically unilaterally, without a definitive or identifiable cause upon investigation, as is the case for 90% of sudden sensorineural hearing loss patients. The degree of hearing loss is typically defined as a loss of 30 decibels or more across 3 contiguous frequencies on audiogram. The hearing loss initially occurring on one side can occur subsequently on the contralateral side in the future. The exact etiology of ISSHL has not been elucidated but of the major proposed mechanisms may be mitigated by HBOT. ISSHL is included in the FDA approved uses of HBOT.

Central Retinal Artery Occlusion (CRAO) and Other Retinal Conditions

CRAO is relatively rare yet devastating diagnosis with poor prognosis for spontaneous recovery. Factors which influence outcome include the length of time of occlusion, the anatomical site of the occlusion, and the presence of a patent cilioretinal artery. The diagnosis of CRAO is typically and reliably made with a fundoscopic exam. Advanced diagnostic studies can confirm CRAO but are not required for the diagnosis. Treatments for CRAO include ocular massage, anterior chamber paracentesis, fibrinolysis, and ocular pressure lowering agents. However, none of these demonstrate improved outcomes compared to control. The FDA has added CRAO to the list of cleared indications for HBOT.

CRAO is a rare complication associated with CaHA (calcium hydroxylapatite) cosmetic filler injection, likely due to embolism.

In addition to CRAO, there are related clinical syndromes for which HBOT could be considered. This includes individuals with branch retinal artery occlusion, particularly those with complete or near complete blindness in the contralateral eye. Also, Susac's Syndrome which is a rare disorder thought to be an autoimmune endotheliopathy causing vascular injury and deposition of thrombotic material in the lumen of small vessels. Treatments for this syndrome include steroids, anticoagulation, and IVIG; HBOT might improve visual acuity for these individuals.

Acute Peripheral Artery Insufficiency

For this policy review, the indication of acute peripheral artery insufficiency is too broad to include as a stand-alone indication for HBOT.

Acute peripheral artery insufficiency is not included in the FDA list of approved conditions for HBOT. The Undersea and Hyperbaric Medical Society guidelines (15th edition) include peripheral artery insufficiency as an indication for HBOT related to diabetic foot ulcers and non-healing arterial insufficiency ulcers but does not have a stand-alone indication for acute peripheral artery insufficiency.

Acute arterial Insufficiencies (AAI) are interruptions, complete or partial, of perfusion that put the tissues distal to the interruption at risk for loss of function or dying. AAIs thereby span all arteries including a variety of conditions already included in this review (e.g., central retinal artery occlusion, ischemic stroke, compartment syndrome). Acute peripheral artery insufficiency (also called peripheral arterial insufficiency) would be a subtype of AAI. Peripheral artery insufficiency is also referred to as peripheral artery disease (PAD). PAD is defined by the American Heart Association as a narrowing of the peripheral arteries that carry blood away from the heart to other parts of the body and is typically further defined to narrowed arteries reducing blood flow to the arms or legs. The AHA states the most common type of PAD is lower-extremity PAD. In 2024, the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines published a Guideline for the Management of Lower Extremity PAD.[2] The Guideline suggests that HBOT may have a limited role, and states HBOT: "may be considered as an adjunctive therapy to revascularization for wound healing in the context of CLTI (chronic limb threatening ischemia) and diabetic foot ulcers". No other mention of HBOT is made, including no mention of HBOT for acute limb ischemia.

Timing and Duration of HBOT Treatment

While broad indications are given above, the decision to treat with HBOT and timing of HBOT should be made on a case-by-case basis. For example, acute arterial ischemias have a spectrum of times that vary by tissue type: minutes for neurological tissues, hours for muscle, days for skin and bone, and even longer for relatively avascular connective tissues, cartilage, and adnexal structures. Even for indications with guideline-based time periods there are case studies showing improvement outside of such windows. For example, the Undersea and Hyperbaric Medical Society Committee recommends HBOT treatment for central retinal artery occlusion (CRAO) within 24 hours of onset, as studies demonstrate the outcome of HBOT is improved with

early treatment. However, successful cases have been reported in which treatment began later, sometimes up to weeks later. Given the safety of HBOT, the lack of successful alternative medical treatments, the debilitating impact of vision loss, and the challenges faced in getting a patient to a hyperbaric facility, it is difficult to provide a specific time cutoff after which HBOT should not be tried for CRAO.

As such, no broad statements or specific statements as to timing of HBOT can be provided.

Recommended treatment dose and number of treatment sessions per the UHMS Hyperbaric Oxygen Therapy Committee (15th edition, 2023) include:

- Acute traumatic ischemia – there are 3 stages of wound healing. Treatment recommended varies based on stage, and ranges from 2-3 times per day for 2-3 days for acute inflammatory stage, 14 days for repair stage, and up to a month for remodeling.
- Carbon monoxide poisoning – Use up to 3 ATA for 1 to 3 sessions or to clinical plateau.
- Central Retinal Artery Occlusion (CRAO)– Recommend 2 to 2.8 ATA or US Navy Table 6 or equivalent. Treat twice daily to clinical plateau, which typically occurs in less than a week, plus 3 days. Hyperbaric treatments 2-3 times daily may be necessary until the angiogram normalizes or the patient has no further improvement for 3 treatments.
- Clostridial myositis, Clostridial myonecrosis (Gas gangrene)- Recommend 3 ATA pressure for 90 minutes, 2-3 times in the first 24 hours, and then 2 times daily for the next 2-5 days. Review is indicated after 10 treatments.
- Chronic refractory osteomyelitis – Typically, once daily, 5-7 days per week for 90-120 minutes using 2-3 ATA, and continued for 4-6 weeks. 20-40 sessions typically needed, although might be situations where up to 60 sessions are needed. Patients with refractory stage 3 or 4 osteomyelitis are most likely to benefit from adjunctive hyperbaric oxygen therapy, especially when complicated by adverse local or systemic factors.
- Compartment syndrome – Use 2 to 2.4 ATA, usually twice a day for 2 days but sometimes might need 3 times a day. After fasciotomy, twice a day for 7-14 days.
- Compromised skin grafts and flaps – Use 2 to 2.5 ATA twice daily for up to 20 sessions.
- Crush injury – similar to acute traumatic ischemia above. The UHMS notes that HBOT should be started as close as possible to the time of injury; 3 or more treatments during the first 24 to 72 hours are recommended; 1-2 times per day for 14 days if in the repair phase; daily use for 3-6 weeks during remodeling.
- Cyanide poisoning – Patients with cyanide poisoning frequently present with simultaneous carbon monoxide poisoning. Treatment protocol recommended is the same as for carbon monoxide poisoning.

- Decompression sickness – Use US Navy Treatment Table 6 or equivalent, typically up to 2.8 ATA, for 1 session up to a clinical plateau. Typically, no more than 1 to 2 treatment sessions are needed.
- Diabetic lower extremity wounds, selected individuals and healing of other problem wounds –Use 2 to 2.5 ATA daily, should see effects by 2-3 weeks; course of outpatient therapy is typically 30 sessions but might require up to 40 sessions. For HBOT to continue, reevaluation at 30-day intervals must show continued progress in healing.
- Necrotizing soft-tissue infections – Use 2 to 2.5 ATA twice daily until stabilization occurs, often occurs within 7-10 treatments. If differential diagnosis includes the possibility of Clostridial myositis and/or myonecrosis and/or remains unclear, 2.8-3 ATA pressures are warranted with 3 treatments in the first 24-48 hours. Avoidance of premature cessation of HBOT is advised, and once extension of necrosis has been halted then once daily treatments over an extended period until the infection is well controlled is recommended. This might require 30 treatments. Review after 30 treatments.
- Radiation Necrosis –Most treatments range from 2-2.5 ATA for 40-60 treatments, and review should occur after 60 treatments.
    - Mandibular osteoradionecrosis, laryngeal necrosis, other soft tissue head and neck, chest wall necrosis, radiation cystitis, radiation proctitis, miscellaneous abdominal pelvic injuries, cutaneous necrosis – 2 to 2.4 ATA daily for 90 minutes.
    - Neoadjuvant hyperbaric oxygen therapy before dental extractions – 2 to 2.4 ATA, typically 20 treatments before extraction and 10 treatments after.
- Sudden sensorineural heating loss – Recommend 2 to 2.5 ATA for 10 to 20 sessions.
- Severe Anemia – Use 2 to 3 ATA for 3 or 4 times a day until there is replacement of red blood cells by regeneration or transfusion.[1,3]

Evidence Review

Description

Hyperbaric oxygen therapy (HBOT) involves breathing 100% oxygen at pressures between 1.5 and 3.0 atmospheres. It is generally applied systemically with the individual inside a hyperbaric chamber. HBOT can also be applied topically, i.e., the body part to be treated is isolated (e.g., in an inflatable bag and exposed to pure oxygen). HBOT has been investigated for various conditions that have potential to respond to increased oxygen delivery to tissue.

Background

Hyperbaric Oxygen Therapy

HBOT is a technique for delivering higher pressures of oxygen to tissue. Two methods of administration are available: systemic and topical.

Topical Hyperbaric Oxygen Therapy

Topical hyperbaric therapy is a technique of delivering 100% oxygen directly to an open, moist wound at a pressure slightly higher than atmospheric pressure. It is hypothesized that the high concentrations of oxygen diffuse directly into the wound to increase the local cellular oxygen tension, which in turn promotes wound healing. Devices consist of an appliance to enclose the wound area (frequently an extremity) and a source of oxygen; conventional oxygen tanks may be used. The appliances may be disposable and may be used without supervision in the home by well-trained individuals. Topical hyperbaric therapy has been investigated as a treatment of skin ulcerations resulting from diabetes, venous stasis, postsurgical infection, gangrenous lesion, decubitus ulcers, amputations, skin graft, burns, or frostbite.

Systemic Hyperbaric Oxygen Therapy

In systemic or large hyperbaric oxygen chambers, the individual is entirely enclosed in a pressure chamber and breathes oxygen at a pressure greater than 1 atmosphere (the pressure of oxygen at sea level). Thus, this technique relies on systemic circulation to deliver highly oxygenated blood to the target site, typically a wound. Systemic HBOT can be used to treat systemic illness, such as air or gas embolism, carbon monoxide poisoning, or clostridial gas gangrene. Treatment may be carried out either in a monoplace chamber pressurized with pure oxygen or in a larger, multiplace chamber pressurized with compressed air, in which case the individual receives pure oxygen by mask, head tent, or endotracheal tube.

Adverse Events

HBOT is a generally safe therapy, with an estimated adverse side effect rate of 0.4%.[4] Adverse events may occur either from pressure effects or the oxygen. The pressure effect (barotrauma) may affect any closed air-filled cavity such as ears, sinus, teeth, and lungs. Pain and/or swelling may occur at these sites as pressure increases during the procedure and decreases as the

procedure is ending. Oxygen toxicity may affect the pulmonary, neurologic, or ophthalmologic systems. Pulmonary symptoms include a mild cough, substernal burning, and dyspnea. Neurologic effects include tunnel vision, tinnitus, nausea, and dizziness. Ophthalmologic effects include retinopathy in neonates, cataract formation, and transient myopic vision changes.

Note: This policy does not address topical oxygen therapy in the absence of pressurization.

Summary of Evidence

For individuals with wounds, burns or infections who receive topical hyperbaric oxygen therapy (HBOT), the evidence includes a systematic review, case series, and a randomized controlled trial (RCT). The relevant outcomes are overall survival (OS), symptoms, change in disease status, and functional outcomes. The systematic review identified three RCTs including individuals with sacral pressure ulcers, ischial pressure ulcers, and refractory venous ulcers. All trials reported that healing improved significantly after HBOT than after standard of care. Pooling of results was not possible due to heterogeneity in individual populations and treatment regimens. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with chronic diabetic ulcers who receive systemic HBOT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms and change in disease status. Meta-analyses of RCTs found significantly higher diabetic ulcer healing rates with HBOT than with control conditions. Two of the three meta-analyses found that HBOT was associated with a significantly lower rate of major amputation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with carbon monoxide poisoning who receive systemic HBOT, the evidence includes RCTs and a systematic review. The relevant outcomes are OS and symptoms. A meta-analysis in a Cochrane review of low-quality RCT data did not find HBOT to be associated with a significantly lower risk of neurologic deficits after carbon monoxide poisoning. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with radionecrosis, osteoradionecrosis, or treatment of irradiated jaw who receive systemic HBOT, the evidence includes RCTs and a systematic review. The relevant outcomes are symptoms and change in disease status. A meta-analysis in a Cochrane review of RCTs found evidence that HBOT improved radionecrosis and osteoradionecrosis outcomes and resulted in better outcomes before tooth extraction in an irradiated jaw. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with chronic refractory osteomyelitis who receive systemic HBOT, the evidence includes case series. The relevant outcomes are symptoms and change in disease status. The case series reported high rates of successful outcomes (no drainage, pain, tenderness, or cellulitis) in individuals with chronic refractory osteomyelitis treated with HBOT. However, controlled studies are needed to determine conclusively the impact of HBOT on health outcomes compared with other interventions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with acute thermal burns who receive systemic HBOT, the evidence includes a systematic review of two RCTs. The relevant outcomes are OS, symptoms, and change in disease status. Both RCTs were judged to have poor methodologic quality. Evidence from well-conducted controlled trials is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with acute surgical and traumatic wounds who receive systemic HBOT, the evidence includes RCTs, controlled nonrandomized studies, and systematic reviews. The relevant outcomes are OS, symptoms, change in disease status, and functional outcomes. There was considerable heterogeneity across the four RCTs identified (e.g., patient population, comparison group, treatment regimen, outcomes). This heterogeneity prevented pooling of trial findings and limits the ability to definitively conclude the impact of HBOT on health outcomes for individuals with acute surgical and traumatic wounds. Additional evidence from high-quality RCTs is needed. A systematic review of controlled Chinese studies suggests HBOT may increase the survival rate of compromised skin grafts and flaps when initiated within 72 hours; however, risk of bias in the original Chinese publications cannot be evaluated. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with bisphosphonate-related osteonecrosis of the jaw who receive systemic HBOT, the evidence includes an RCT. The relevant outcomes are symptoms and change in disease status. The RCT was unblinded and reported initial benefits at three-month follow-up; however, there were no significant benefits of HBOT for most health outcomes compared with standard care in the long-term (six months to two years). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with necrotizing soft tissue infections who receive systemic HBOT, the evidence includes systematic reviews. The relevant outcomes are OS, symptoms, and change in disease status. A Cochrane review did not identify any RCTs. Another systematic review of retrospective cohort studies with methodological limitations did not find consistent benefit of adjunctive HBOT use. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with acute coronary syndrome who receive systemic HBOT, the evidence includes RCTs and a systematic review. The relevant outcomes are OS, symptoms, change in disease status, and functional outcomes. A Cochrane review identified six RCTs. There were two pooled analyses, one found significantly lower rates of death with HBOT and the other reported inconsistent results in left ventricular function. Additional RCT data are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with acute ischemic stroke who receive systemic HBOT, the evidence includes RCTs and a systematic review. The relevant outcomes are OS, symptoms, change in disease status, and functional outcomes. Cochrane reviewers could only pool data for a single outcome (mortality at three-six months), and for that outcome, there was no significant difference between active and sham HBOT treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with motor dysfunction associated with stroke who receive systemic HBOT, the evidence includes an RCT. The relevant outcomes are symptoms and functional outcomes. The RCT which used a crossover design, found better outcomes with HBOT at two months than with delayed treatment. However, the trial had a number of methodologic limitations (e.g., lack of patient blinding, heterogeneous population, high dropout rate) that make it difficult to evaluate the efficacy of HBOT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with Bell's palsy who receive systemic HBOT, the evidence includes a systematic review. The relevant outcomes are symptoms, change in disease status, and functional outcomes. A Cochrane review did not identify any RCTs meeting selection criteria; the single RCT found did not have a blinded outcome assessment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with traumatic brain injury who receive systemic HBOT, the evidence includes RCTs and systematic reviews. The relevant outcomes are OS, symptoms, change in disease status, and functional outcomes. RCTs were heterogenous regarding intervention protocols, patient populations, and outcomes reported. Systematic reviews conducted pooled analyses only on a minority of the published RCTs, and these findings were inconsistent. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with inflammatory bowel disease who receive systemic HBOT, the evidence includes RCTs, observational studies, and a systematic review. The relevant outcomes are symptoms, change in disease status and functional outcomes. Three RCTs have reported mixed

findings in individuals with ulcerative colitis, with one study terminated early due to futility. A systematic review including the RCT, and observational studies found a high rate of bias in the literature due to attrition and reporting bias. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with idiopathic sudden sensorineural hearing loss who receive systemic HBOT, the evidence includes systematic reviews. Relevant outcomes are symptoms, change in disease status, and functional outcomes. A Cochrane review of RCTs had mixed findings from studies that included individuals with tinnitus. Some outcomes (i.e., improvement in hearing of all frequencies, >25% return of hearing) were better with HBOT than with a control intervention, but more than 50% return of hearing did not differ significantly between groups. There was important variability in the individuals enrolled in the studies. A subsequent systematic review had similarly limited conclusions due to the inclusion of non-randomized studies. A third review found a higher proportion of individuals with hearing recovery with HBOT compared to medical treatment alone, but the analysis was limited to two RCTs with methodological limitations. One RCT published subsequent to the systematic reviews found a positive effect of HBOT plus steroid combination therapy on measures of auditory function compared to either HBOT or steroids alone, but other outcomes were not reported, and the study had numerous relevance, design, and conduct limitations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with delayed-onset muscle soreness who receive systemic HBOT, the evidence includes RCTs and a systematic review. The relevant outcomes are symptoms and functional outcomes. A Cochrane review of RCTs found worse short-term pain outcomes with HBOT than with control and no difference in longer-term pain or other outcomes (e.g., swelling). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with autism spectrum disorder who receive systemic HBOT, the evidence includes an RCT and a systematic review. The relevant outcomes are symptoms and functional outcomes. A Cochrane review identified a single RCT on HBOT for autism spectrum disorder and this trial did not find significantly better parental-assessed or clinician-assessed outcomes with HBOT compared with sham. A subsequent controlled trial reached the same conclusion. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with cerebral palsy who receive systemic HBOT, the evidence includes two RCTs and an observational study. The relevant outcomes are symptoms and functional outcomes. One RCT was stopped early due to futility, and the other did not find significantly better outcomes with HBOT than with a sham intervention. The observational study focused on sleep disorders in

children with cerebral palsy and reported improvements with the HBOT treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with vascular dementia who receive systemic HBOT, the evidence includes an RCT and a systematic review. The relevant outcomes are symptoms and functional outcomes. The Cochrane review identified only a single RCT with methodologic limitations. Well-conducted controlled trials are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with radiotherapy adverse events who receive systemic HBOT, the evidence includes RCTs, nonrandomized comparator trials, case series, and systematic reviews. The relevant outcomes are symptoms and functional outcomes. Two systematic reviews included few RCTs and provide limited evidence on the effect of HBOT. Two RCTs identified had inconsistent findings. One reported no short-term benefit with HBOT, but some benefits 12 months after radiotherapy; the other did not find a significant benefit of HBOT at 12-month follow-up. Another RCT assessed HBOT for radiation-induced cystitis and found significant benefit by some measures but not others. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with idiopathic femoral neck necrosis who receive systemic HBOT, the evidence includes an RCT. The relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCT, which had a small sample, only reported short-term (i.e., six-week) outcomes. Larger well-conducted RCTs reporting longer-term outcomes are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with a migraine who receive systemic HBOT, the evidence includes RCTs and a systematic review. The relevant outcomes are symptoms, change in disease status, and functional outcomes. The Cochrane review conducted a pooled analysis including 3 of the 11 trials. Meta-analysis of these three RCTs found significantly greater relief of migraine symptoms with HBOT than with a comparator intervention within 45 minutes of treatment. Longer-term data are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with herpes zoster who receive systemic HBOT, the evidence includes an RCT. The relevant outcomes are symptoms and change in disease status. The RCT was unblinded and only reported short-term (i.e., six-week) outcomes. Additional well-conducted RCTs with longer follow-up are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with fibromyalgia who receive systemic HBOT, the evidence includes RCTs. The relevant outcomes are symptoms, change in disease status, and functional outcomes. Only two RCTs were identified, and both reported positive effects of HBOT on tender points and pain. However, the trials had relatively small samples and methodologic limitations (e.g., quasi-randomization, no or uncertain sham control for a condition with subjective outcomes susceptible to a placebo effect). Moreover, the HBOT protocols varied. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with multiple sclerosis who receive systemic HBOT, the evidence includes RCTs and a systematic review. The relevant outcomes are symptoms and functional outcomes. A Cochrane review of RCTs did not find a significant difference in Expanded Disability Status Scale scores when individuals with multiple sclerosis were treated with HBOT versus a comparator intervention. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with cancer undergoing chemotherapy who receive systemic HBOT, the evidence includes an RCT and a systematic review. The relevant outcomes are OS and change in disease status. While the systematic review reported improvements in tumor control in individuals with head and neck cancer who received HBOT, the adverse events accompanying the treatment (e.g., radiation tissue injury, seizures) were significant. The single RCT did not find a significant difference in survival for cancer individuals who received HBOT before chemotherapy compared with usual care. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02407028	Hyperbaric Oxygen Brain Injury Treatment (HOBIT) Trial	200	June 2027

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04975867	Targeted Temperature Management Combined With Hyperbaric Oxygen Therapy in Acute Severe Carbon Monoxide Poisoning: Multicenter Randomized Controlled Clinical Trial (TTM-COHB Trial)	46	Jul 2025
NCT05289700	Multicentric, Double-blind, Randomised Controled Trial of Hyperbaric-oxygen Therapy (HBOT) Versus Placebo for Treating Vaso-Occlusive Crisis (VOC) in Sickle Cell Disease (SCD) After 8 Years Old	100	Mar 2025
Unpublished			
NCT04193722	The Effect of Hyperbaric Oxygen Therapy on Breast Cancer Patients With Late Radiation Toxicity	189	May 2023

NCT: national clinical trial.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2024 Input

Clinical input was sought to help determine whether the use of systemic HBOT in individuals with necrotizing soft tissue infections, idiopathic sudden sensorineural hearing loss, central retinal artery occlusion, or acute peripheral artery insufficiency would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 2 respondents, including 2 specialty society-level responses.

For individuals with necrotizing soft tissue infections, idiopathic sudden sensorineural hearing loss, central retinal artery occlusion, or acute arterial insufficiency who receive HBOT, clinical input supports this use provides a clinically meaningful improvement in net health outcomes and indicates this use is consistent with generally accepted medical practice.

Further details from clinical input are included in the Appendix.

2023 Input

Clinical input was sought to help determine whether the use of systemic hyperbaric oxygen therapy (HBOT) in individuals with acute surgical or traumatic wounds and compromised skin grafts or flaps would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from two respondents, including two specialty society-level responses.

For individuals with acute surgical or traumatic wounds and compromised skin grafts or flaps who receive systemic HBOT, clinical input supports this use provides a clinically meaningful improvement in net health outcomes and indicates this use is consistent with generally accepted medical practice.

2010 Input

In response to requests, input was received from six physician specialty societies and five academic medical centers while this policy was under review in 2010. Clinical input varied by condition. There was consensus that topical hyperbaric oxygen therapy (HBOT) and systemic HBOT for autism spectrum disorder and headache/migraine are investigational. There was also wide support for adding acute carbon monoxide poisoning, compromised skin grafts or flaps, chronic refractory osteomyelitis, and necrotizing soft tissue infections to the list of medically necessary indications for HBOT. Several reviewers acknowledged that there is a paucity of clinical trials on HBOT for compromised skin grafts/flaps, necrotizing soft tissue infections, and chronic refractory osteomyelitis. These reviewers commented on the support from basic science, animal studies, and retrospective case series, as well as lack of effective alternative treatments for these conditions. Based on the available evidence and clinical input, acute carbon monoxide poisoning, and chronic refractory osteomyelitis were changed in 2010 to medically necessary indications for HBOT. However, despite the clinical input and given the limited published evidence, compromised skin grafts and flaps and necrotizing soft tissue infections are still considered investigational.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Society of Vascular Surgery et al

In 2016, the Society of Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine published guidelines on the management of the diabetic foot.[72] According to the guidelines, for diabetic foot ulcers that fail to demonstrate improvement (>50% wound area reduction) after a minimum of four weeks of standard wound therapy, adjunctive therapy such as HBOT is recommended (grade 1B). Also, for diabetic foot ulcers with adequate perfusion that fail to respond to four to six weeks of conservative management, HBOT is suggested (grade 2B).

Undersea and Hyperbaric Medical Society (UHMS)

In 2015, the UHMS published guidelines on the use of hyperbaric oxygen therapy (HBOT) for treating diabetic foot ulcers.[73] Recommendations in the current version include:

- Suggest against using HBOT in patients with "Wagner Grade 2 or lower diabetic foot ulcers..."
- Suggest adding HBOT in patients with "Wagner Grade 3 or higher diabetic foot ulcers that have not shown significant improvement after 30 days of [standard of care] therapy..."
- Suggest "adding acute post-operative hyperbaric oxygen therapy to the standard of care" in patients with "Wagner Grade 3 or higher diabetic foot ulcers" who have just had foot surgery related to their diabetic ulcers.

Undersea and Hyperbaric Medical Society

The 2023 UHMS Hyperbaric Oxygen Therapy Indications (15th edition) included the following indications as recommended[1]:

- Acute thermal burn injury
- Acute traumatic ischemias
- Air or gas embolism
- Arterial insufficiencies: Central Retinal Artery Occlusion; Hyerbaric oxygen Therapy for Selected Problem Wounds
- Avascular necrosis (aseptic osteonecrosis)
- Carbon monoxide poisoning and carbon monoxide complicated by cyanide poisoning
- Compromised grafts and flaps
- Clostridial myositis and myonecrosis (gas gangrene)
- Decompression sickness
- Delayed rdiation injury (soft tissue and bony necrosis)
- Intracranial abscess
- Necrotizing soft tissue infections
- Refractory osteomyelitis
- Severe anemia
- Sudden sensorineural hearing loss.

American Academy of Otolaryngology-Head and Neck Surgery

In 2019, the American Academy of Otolaryngology-Head and Neck Surgery updated clinical guidelines on the treatment of sudden sensorineural hearing loss (SSNHL).[70] They give the following options regarding HBOT:

"Clinicians may offer, or refer to a physician who can offer, hyperbaric oxygen therapy (HBOT) combined with steroid therapy within 2 weeks of onset of SSNHL."

"Clinicians may offer, or refer to a physician who can offer, hyperbaric oxygen therapy (HBOT) combined with steroid therapy as salvage within 1 month of onset of SSNHL."

The guideline provided a comprehensive list of evidence gaps and future research needs on the use of HBOT for SSNHL. These included, among others, the need for a standardized, evidence-based definition of SSNHL, the assessment of the prevalence of SSNHL, and the need for the development of standardized HBOT treatment protocols and standardized outcome assessments.

American College of Cardiology/American Heart Association

In 2024, the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines published a Guideline for the Management of Lower Extremity PAD.[2] The Guideline was developed in collaboration with and endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Podiatric Medical Association, Association of Black Cardiologists, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine, Society for Vascular Nursing, Society for Vascular Surgery, Society of Interventional Radiology, and Vascular & Endovascular Surgery Society. The Guideline included the following statements relevant to this evidence review:

"Beyond wound care, hyperbaric oxygen therapy has been studied in the context of wound healing for CLTI as an adjunctive therapy to revascularization and may have a limited role in this population."

"Hyperbaric oxygen therapy may be considered as an adjunctive therapy to revascularization for wound healing in the context of CLTI (chronic limb threatening ischemia) and diabetic foot ulcers."

American College of Cardiology/American Stroke Association

In 2019 the American Heart Association and American Stroke Association updated the guidelines for early management of acute ischemic stroke.[71] The guidelines were endorsed by the Society for Academic Emergency Medicine, the Neurocritical Care Society, the American Association of Neurological Surgeons, and the Congress of Neurological Surgeons. The Guideline included the following statements relevant to this policy:

"The limited data available on the utility of HBO therapy for acute ischemic stroke (not related to cerebral air embolism) show no benefit. HBO therapy is associated with claustrophobia and middle ear barotrauma, as well as an increased risk of seizures. Given the confines of HBO chambers, the ability to closely/adequately monitor patients may also be compromised. HBO thus should be offered only in the context of a clinical trial or to individuals with cerebral air embolism."

Medicare National Coverage

In 2003 (updated in 2017), the Centers for Medicare & Medicaid added Medicare coverage of HBOT for diabetic wounds of the lower extremities meeting certain criteria. As of the current coverage statement, Medicare coverage is provided for HBOT administered in a chamber for the following conditions[74]:

- Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment,
- Acute carbon monoxide intoxication,
- Acute peripheral arterial insufficiency,
- Acute traumatic peripheral ischemia. HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened.
- Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management,
- Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened.
- Cyanide poisoning,
- Decompression illness,
- Diabetic wounds of the lower extremities in patients who meet the following three criteria:
    - Individual has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
    - Individual has a wound classified as Wagner grade III or higher; and
    - Individual has failed an adequate course of standard wound therapy
- Gas embolism,
- Gas gangrene,
- Osteoradionecrosis as an adjunct to conventional treatment,
- Preparation and preservation of compromised skin grafts (not for primary management of wounds),

- Progressive necrotizing infections (necrotizing fasciitis),
- Soft tissue radionecrosis as an adjunct to conventional treatment,

The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30-days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in individuals with diabetic wounds includes assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during the administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment."

Systemic HBOT for other indications is not covered, nor is topical HBOT for any indication.

Regulatory Status

Since 1979, the US Food and Drug Administration (FDA) has cleared multiple topical and systemic hyperbaric oxygen administration devices through the 510(k) pathway. In 2013, the FDA published a statement warning that non-FDA approved uses of HBOT may endanger the health of patients.[5] If patients mistakenly believe that HBOT devices have been proven safe for uses not cleared by the FDA, they may delay or forgo proven medical therapies.

As of July 2021, the FDA has cleared hyperbaric chambers for the following disorders:

- Air and gas bubbles in blood vessels
- Anemia (severe anemia when blood transfusions cannot be used)
- Burns (severe and large burns treated at a specialized burn center)
- Carbon monoxide poisoning
- Crush injury
- Decompression sickness (diving risk)

- Gas gangrene
- Hearing loss (complete hearing loss that occurs suddenly and without any known cause)
- Infection of the skin and bone (severe)
- Radiation injury
- Skin graft flap at risk of tissue death
- Vision loss (when sudden and painless in one eye due to blockage of blood flow)
- Wounds (non-healing, diabetic foot ulcers).

References

1. Undersea and Hyperbaric Medical Society. Hyperbaric Oxygen Therapy Indications, 15th Edition. Best Publishing Company (North Palm Beach, FL). 2023.
2. Gornik HL, Aronow HD, Goodney PP, et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. Jun 11 2024; 149(24): e1313-e1410. PMID 38743805
3. United States Navy Dive Manual, Revision 7. 2016
4. Sadri RA, Cooper JS. Hyperbaric, complications. NCBI Bookshelf 2017; **https://www.ncbi.nlm.nih.gov/books/NBK459191/**. Accessed October 11, 2024.
5. U.S. Food and Drug Administration. Hyperbaric Oxygen Therapy: Don't Be Misled. 2013; **https://www.talkingaboutthescience.com/studies/FDA2013.pdf**. Accessed October 11, 2024.
6. de Smet GHJ, Kroese LF, Menon AG, et al. Oxygen therapies and their effects on wound healing. Wound Repair Regen. Aug 2017; 25(4): 591-608. PMID 28783878
7. Sharma R, Sharma SK, Mudgal SK, et al. Efficacy of hyperbaric oxygen therapy for diabetic foot ulcer, a systematic review and meta-analysis of controlled clinical trials. Sci Rep. Jan 26 2021; 11(1): 2189. PMID 33500533
8. Kranke P, Bennett MH, Martyn-St James M, et al. Hyperbaric oxygen therapy for chronic wounds. Cochrane Database Syst Rev. Jun 24 2015; 2015(6): CD004123. PMID 26106870
9. Elraiyah T, Tsapas A, Prutsky G, et al. A systematic review and meta-analysis of adjunctive therapies in diabetic foot ulcers. J Vasc Surg. Feb 2016; 63(2 Suppl): 46S-58S.e1-2. PMID 26804368
10. Buckley NA, Juurlink DN, Isbister G, et al. Hyperbaric oxygen for carbon monoxide poisoning. Cochrane Database Syst Rev. Apr 13 2011; 2011(4): CD002041. PMID 21491385
11. Nakajima M, Aso S, Matsui H, et al. Hyperbaric oxygen therapy and mortality from carbon monoxide poisoning: A nationwide observational study. Am J Emerg Med. Feb 2020; 38(2): 225-230. PMID 30797609
12. Bennett MH, Feldmeier J, Hampson NB, et al. Hyperbaric oxygen therapy for late radiation tissue injury. Cochrane Database Syst Rev. Apr 28 2016; 4(4): CD005005. PMID 27123955

13. Borab Z, Mirmanesh MD, Gantz M, et al. Systematic review of hyperbaric oxygen therapy for the treatment of radiation-induced skin necrosis. J Plast Reconstr Aesthet Surg. Apr 2017; 70(4): 529-538. PMID 28081957

14. Ravi P, Vaishnavi D, Gnanam A, et al. The role of hyperbaric oxygen therapy in the prevention and management of radiation-induced complications of the head and neck - a systematic review of literature. J Stomatol Oral Maxillofac Surg. Dec 2017; 118(6): 359-362. PMID 28838774

15. Savvidou OD, Kaspiris A, Bolia IK, et al. Effectiveness of Hyperbaric Oxygen Therapy for the Management of Chronic Osteomyelitis: A Systematic Review of the Literature. Orthopedics. Jul 01 2018; 41(4): 193-199. PMID 30035798

16. Maynor ML, Moon RE, Camporesi EM, et al. Chronic osteomyelitis of the tibia: treatment with hyperbaric oxygen and autogenous microsurgical muscle transplantation. J South Orthop Assoc. 1998; 7(1): 43-57. PMID 9570731

17. Davis JC, Heckman JD, DeLee JC, et al. Chronic non-hematogenous osteomyelitis treated with adjuvant hyperbaric oxygen. J Bone Joint Surg Am. Oct 1986; 68(8): 1210-7. PMID 3771602

18. Chen CE, Ko JY, Fu TH, et al. Results of chronic osteomyelitis of the femur treated with hyperbaric oxygen: a preliminary report. Chang Gung Med J. Feb 2004; 27(2): 91-7. PMID 15095953

19. Chen CE, Shih ST, Fu TH, et al. Hyperbaric oxygen therapy in the treatment of chronic refractory osteomyelitis: a preliminary report. Chang Gung Med J. Feb 2003; 26(2): 114-21. PMID 12718388

20. Chen CY, Lee SS, Chan YS, et al. Chronic refractory tibia osteomyelitis treated with adjuvent hyperbaric oxygen: a preliminary report. Changgeng Yi Xue Za Zhi. Jun 1998; 21(2): 165-71. PMID 9729650

21. Villanueva E, Bennett MH, Wasiak J, et al. Hyperbaric oxygen therapy for thermal burns. Cochrane Database Syst Rev. 2004; 2004(3): CD004727. PMID 15266540

22. Eskes A, Vermeulen H, Lucas C, et al. Hyperbaric oxygen therapy for treating acute surgical and traumatic wounds. Cochrane Database Syst Rev. Dec 16 2013; (12): CD008059. PMID 24343585

23. Dauwe PB, Pulikkottil BJ, Lavery L, et al. Does hyperbaric oxygen therapy work in facilitating acute wound healing: a systematic review. Plast Reconstr Surg. Feb 2014; 133(2): 208e-215e. PMID 24469192

24. Zhou YY, Liu W, Yang YJ, et al. Use of hyperbaric oxygen on flaps and grafts in China: analysis of studies in the past 20 years. Undersea Hyperb Med. 2014; 41(3): 209-16. PMID 24984315

25. Freiberger JJ, Padilla-Burgos R, McGraw T, et al. What is the role of hyperbaric oxygen in the management of bisphosphonate-related osteonecrosis of the jaw: a randomized controlled trial of hyperbaric oxygen as an adjunct to surgery and antibiotics. J Oral Maxillofac Surg. Jul 2012; 70(7): 1573-83. PMID 22698292

26. Levett D, Bennett MH, Millar I. Adjunctive hyperbaric oxygen for necrotizing fasciitis. Cochrane Database Syst Rev. Jan 15 2015; 1(1): CD007937. PMID 25879088

27. Hedetoft M, Bennett MH, Hyldegaard O. Adjunctive hyperbaric oxygen treatment for necrotising soft-tissue infections: A systematic review and meta-analysis. Diving Hyperb Med. Mar 31 2021; 51(1): 34-43. PMID 33761539

28. Bennett MH, Lehm JP, Jepson N. Hyperbaric oxygen therapy for acute coronary syndrome. Cochrane Database Syst Rev. Jul 23 2015; 2015(7): CD004818. PMID 26202854

29. Bennett MH, Weibel S, Wasiak J, et al. Hyperbaric oxygen therapy for acute ischaemic stroke. Cochrane Database Syst Rev. Nov 12 2014; 2014(11): CD004954. PMID 25387992

30. Efrati S, Fishlev G, Bechor Y, et al. Hyperbaric oxygen induces late neuroplasticity in post stroke patients--randomized, prospective trial. PLoS One. 2013; 8(1): e53716. PMID 23335971

31. Holland NJ, Bernstein JM, Hamilton JW. Hyperbaric oxygen therapy for Bell's palsy. Cochrane Database Syst Rev. Feb 15 2012; 2012(2): CD007288. PMID 22336830

32. Wang F, Wang Y, Sun T, et al. Hyperbaric oxygen therapy for the treatment of traumatic brain injury: a meta-analysis. Neurol Sci. May 2016; 37(5): 693-701. PMID 26746238

33. Crawford C, Teo L, Yang E, et al. Is Hyperbaric Oxygen Therapy Effective for Traumatic Brain Injury? A Rapid Evidence Assessment of the Literature and Recommendations for the Field. J Head Trauma Rehabil. 2017; 32(3): E27-E37. PMID 27603765

34. Bennett MH, Trytko B, Jonker B. Hyperbaric oxygen therapy for the adjunctive treatment of traumatic brain injury. Cochrane Database Syst Rev. Dec 12 2012; 12: CD004609. PMID 23235612

35. Hart BB, Weaver LK, Gupta A, et al. Hyperbaric oxygen for mTBI-associated PCS and PTSD: Pooled analysis of results from Department of Defense and other published studies. Undersea Hyperb Med. BIMA 2019; 46(3): 353-383. PMID 31394604

36. mTBI mechanisms of action of HBO2 for persistent post-concussive symptoms. U.S. National Library of Medicine. ClinicalTrials.gov. **https://clinicaltrials.gov/ct2/show/NCT01611194**. Accessed October 11, 2024.

37. Hart BB, Wilson SH, Churchill S, et al. Extended follow-up in a randomized trial of hyperbaric oxygen for persistent post-concussive symptoms. Undersea Hyperb Med. BIMA 2019; 46(3): 313-327. PMID 31394601

38. Churchill S, Deru K, Weaver LK, et al. Adverse events and blinding in two randomized trials of hyperbaric oxygen for persistent post-concussive symptoms. Undersea Hyperb Med. BIMA 2019; 46(3): 331-340. PMID 31394602

39. Weaver LK, Churchill S, Wilson SH, et al. A composite outcome for mild traumatic brain injury in trials of hyperbaric oxygen. Undersea Hyperb Med. BIMA 2019; 46(3): 341-352. PMID 31394603

40. Hyperbaric oxygen therapy (HBO2) for persistent post-concussive symptoms after mild traumatic brain injury (mTBI) (HOPPS). U.S. National Library of Medicine. **Study Details | Hyperbaric Oxygen Therapy (HBO2) for Persistent Post-concussive Symptoms After Mild Traumatic Brain Injury (mTBI) | ClinicalTrials.gov**. Updated September 5, 2014. Accessed October 11, 2024.

41. McCurdy J, Siw KCK, Kandel R, et al. The Effectiveness and Safety of Hyperbaric Oxygen Therapy in Various Phenotypes of Inflammatory Bowel Disease: Systematic Review With Meta-analysis. Inflamm Bowel Dis. Mar 30 2022; 28(4): 611-621. PMID 34003289

42. Dulai PS, Buckey JC, Raffals LE, et al. Hyperbaric oxygen therapy is well tolerated and effective for ulcerative colitis patients hospitalized for moderate-severe flares: a phase 2A pilot multi-center, randomized, double-blind, sham-controlled trial. Am J Gastroenterol. Oct 2018; 113(10): 1516-1523. PMID 29453383

43. Dulai PS, Raffals LE, Hudesman D, et al. A phase 2B randomised trial of hyperbaric oxygen therapy for ulcerative colitis patients hospitalised for moderate to severe flares. Aliment Pharmacol Ther. Sep 2020; 52(6): 955-963. PMID 32745306

44. Pagoldh M, Hultgren E, Arnell P, et al. Hyperbaric oxygen therapy does not improve the effects of standardized treatment in a severe attack of ulcerative colitis: a prospective randomized study. Scand J Gastroenterol. Sep 2013; 48(9): 1033-40. PMID 23879825

45. Bennett MH, Kertesz T, Perleth M, et al. Hyperbaric oxygen for idiopathic sudden sensorineural hearing loss and tinnitus. Cochrane Database Syst Rev. Oct 17 2012; 10: CD004739. PMID 23076907

46. Rhee TM, Hwang D, Lee JS, et al. Addition of Hyperbaric Oxygen Therapy vs Medical Therapy Alone for Idiopathic Sudden Sensorineural Hearing Loss: A Systematic Review and Meta-analysis. JAMA Otolaryngol Head Neck Surg. Dec 01 2018; 144(12): 1153-1161. PMID 30267033

47. Joshua TG, Ayub A, Wijesinghe P, et al. Hyperbaric Oxygen Therapy for Patients With Sudden Sensorineural Hearing Loss: A Systematic Review and Meta-analysis. JAMA Otolaryngol Head Neck Surg. Jan 01 2022; 148(1): 5-11. PMID 34709348

48. Eryigit B, Ziylan F, Yaz F, et al. The effectiveness of hyperbaric oxygen in patients with idiopathic sudden sensorineural hearing loss: a systematic review. Eur Arch Otorhinolaryngol. Dec 2018; 275(12): 2893-2904. PMID 30324404

49. Cavaliere M, De Luca P, Scarpa A, et al. Combination of Hyperbaric Oxygen Therapy and Oral Steroids for the Treatment of Sudden Sensorineural Hearing Loss: Early or Late?. Medicina (Kaunas). Oct 10 2022; 58(10). PMID 36295581

50. Bennett M, Best TM, Babul S, et al. Hyperbaric oxygen therapy for delayed onset muscle soreness and closed soft tissue injury. Cochrane Database Syst Rev. Oct 19 2005; 2005(4): CD004713. PMID 16235376

51. Xiong T, Chen H, Luo R, et al. Hyperbaric oxygen therapy for people with autism spectrum disorder (ASD). Cochrane Database Syst Rev. Oct 13 2016; 10(10): CD010922. PMID 27737490

52. Sampanthavivat M, Singkhwa W, Chaiyakul T, et al. Hyperbaric oxygen in the treatment of childhood autism: a randomised controlled trial. Diving Hyperb Med. Sep 2012; 42(3): 128-33. PMID 22987458

53. Rizzato A, D'Alessandro N, Berenci E, et al. Effect of mild hyperbaric oxygen therapy on children diagnosed with autism. Undersea Hyperb Med. 2018; 45(6): 639-645. PMID 31158930

54. Lacey DJ, Stolfi A, Pilati LE. Effects of hyperbaric oxygen on motor function in children with cerebral palsy. Ann Neurol. Nov 2012; 72(5): 695-703. PMID 23071074

55. Collet JP, Vanasse M, Marois P, et al. Hyperbaric oxygen for children with cerebral palsy: a randomised multicentre trial. HBO-CP Research Group. Lancet. Feb 24 2001; 357(9256): 582-6. PMID 11558483

56. Long Y, Tan J, Nie Y, et al. Hyperbaric oxygen therapy is safe and effective for the treatment of sleep disorders in children with cerebral palsy. Neurol Res. Mar 2017; 39(3): 239-247. PMID 28079475

57. Xiao Y, Wang J, Jiang S, et al. Hyperbaric oxygen therapy for vascular dementia. Cochrane Database Syst Rev. Jul 11 2012; (7): CD009425. PMID 22786527

58. Villeirs L, Tailly T, Ost P, et al. Hyperbaric oxygen therapy for radiation cystitis after pelvic radiotherapy: Systematic review of the recent literature. Int J Urol. Feb 2020; 27(2): 98-107. PMID 31617263

59. Gothard L, Haviland J, Bryson P, et al. Randomised phase II trial of hyperbaric oxygen therapy in patients with chronic arm lymphoedema after radiotherapy for cancer. Radiother Oncol. Oct 2010; 97(1): 101-7. PMID 20605648

60. Oscarsson N, Müller B, Rosén A, et al. Radiation-induced cystitis treated with hyperbaric oxygen therapy (RICH-ART): a randomised, controlled, phase 2-3 trial. Lancet Oncol. Nov 2019; 20(11): 1602-1614. PMID 31537473

61. Camporesi EM, Vezzani G, Bosco G, et al. Hyperbaric oxygen therapy in femoral head necrosis. J Arthroplasty. Sep 2010; 25(6 Suppl): 118-23. PMID 20637561

62. Bennett MH, French C, Schnabel A, et al. Normobaric and hyperbaric oxygen therapy for the treatment and prevention of migraine and cluster headache. Cochrane Database Syst Rev. Dec 28 2015; 2015(12): CD005219. PMID 26709672

63. Peng Z, Wang S, Huang X, et al. Effect of hyperbaric oxygen therapy on patients with herpes zoster. Undersea Hyperb Med. 2012; 39(6): 1083-7. PMID 23342765

64. Efrati S, Golan H, Bechor Y, et al. Hyperbaric oxygen therapy can diminish fibromyalgia syndrome--prospective clinical trial. PLoS One. 2015; 10(5): e0127012. PMID 26010952

65. Yildiz S, Kiralp MZ, Akin A, et al. A new treatment modality for fibromyalgia syndrome: hyperbaric oxygen therapy. J Int Med Res. 2004; 32(3): 263-7. PMID 15174219

66. Bennett M, Heard R. Hyperbaric oxygen therapy for multiple sclerosis. CNS Neurosci Ther. Apr 2010; 16(2): 115-24. PMID 20415839

67. Bennett M, Feldmeier J, Smee R, et al. Hyperbaric oxygenation for tumour sensitisation to radiotherapy. Cochrane Database Syst Rev. Oct 19 2005; (4): CD005007. PMID 16235387

68. Bennett MH, Feldmeier J, Smee R, et al. Hyperbaric oxygenation for tumour sensitisation to radiotherapy. Cochrane Database Syst Rev. Apr 18 2012; 2012(4): CD005007. PMID 22513926

69. Heys SD, Smith IC, Ross JA, et al. A pilot study with long term follow up of hyperbaric oxygen pretreatment in patients with locally advanced breast cancer undergoing neo-adjuvant chemotherapy. Undersea Hyperb Med. 2006; 33(1): 33-43. PMID 16602255

70. Chandrasekhar SS, Tsai Do BS, Schwartz SR, et al. Clinical Practice Guideline: Sudden Hearing Loss (Update). Otolaryngol Head Neck Surg. Aug 2019; 161(1_suppl): S1-S45. PMID 31369359

71. Powers WJ, Rabinstein AA, Ackerson T, et al. Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. Stroke. Dec 2019; 50(12): e344-e418. PMID 31662037

72. Hingorani A, LaMuraglia GM, Henke P, et al. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. J Vasc Surg. Feb 2016; 63(2 Suppl): 3S-21S. PMID 26804367

73. Huang ET, Mansouri J, Murad MH, et al. A clinical practice guideline for the use of hyperbaric oxygen therapy in the treatment of diabetic foot ulcers. Undersea Hyperb Med. 2015; 42(3): 205-47. PMID 26152105

74. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Hyperbaric Oxygen Therapy (20.29). 2017; **https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=12&ver=3**. Accessed October 11, 2024.

History

Date	Comments
05/05/97	Add to Medicine Section - New Policy.
03/03/98	Replace Policy - Reviewed with changes; new indications.
01/04/99	Replace Policy - Policy reviewed; now includes topical hyperbaric oxygen.
09/11/01	Replace Policy - Scheduled update.
12/10/02	Replace Policy - Policy updated; only topical hyperbaric oxygen reviewed; policy statement unchanged.
07/08/03	Replace Policy - Scheduled review, policy statement unchanged.
03/09/04	Replace Policy - Policy reviewed and updated. Medicare policy and Undersea and Hyperbaric Medical Society guidelines added.
09/01/04	Replace Policy - Policy renumbered from PR.2.01.105. No date changes.
03/08/05	Replace Policy - Scheduled review. Policy statement deleted cerebral edema and refractory mycosis as no longer medically necessary. Policy Guidelines and References updated.
03/14/06	Replace Policy - Scheduled review. Codes updated; no change to policy statement.
06/26/06	Update Scope and Disclaimer - No other changes
03/13/07	Replace Policy - Policy updated with literature review; reference updated. No change in policy statement.
02/12/08	Replace Policy - Policy updated with literature search. Policy statement updated to delete “Cyanide Poisoning” as a medically necessary indication. Policy Guidelines and References updated.

Date	Comments
08/11/09	Replace Policy - Policy updated with literature search. Policy statement updated to add medically necessary indication "arterial insufficiency: including chronic nonhealing wounds and central retinal artery occlusion." Reference added.
09/15/09	Minor Updates - Outpatient added to Place of Service.
06/08/10	Replace Policy - Policy updated with literature search. No change to the policy statement. Guidelines contain new recommendation of UR for diabetic wounds after 30 treatments. Reference added. Policy title changed from Hyperbaric Oxygen "Pressurization" to Hyperbaric Oxygen "Therapy." On hold for 90 days, release to publish in November 2010.
11/01/10	Publish Policy - Subsequent to 90-day hold for notification.
07/12/11	Replace Policy - Policy updated with literature review; no change in policy statement.
10/26/12	Replace policy. Added references 25, 26, 27. Policy statement unchanged.
10/14/13	Replace policy. Policy updated with literature review; no change in policy statement.
12/03/13	Coding Update. Add ICD-10 codes.
03/11/14	Coding Update. Code 93.95 was removed per ICD-10 mapping project; this code is not utilized for adjudication of policy.
11/20/14	Annual Review. No change to policy statements. ICD-9 and ICD-10 diagnosis codes removed; these are not utilized in policy adjudication.
01/05/15	Coding update. New HCPCS code G0277, effective 1/1/15, added to the policy.
10/13/15	Annual Review. Policy updated with literature review; no change to policy statement. Information regarding sudden sensorineural hearing loss added to Rationale. References added.
09/01/16	Annual Review, approved August 9, 2016. HCPCS code A4575 added to the policy. No change to policy statements. Literature reviewed, no new additions.
04/01/17	Annual Review, approved March 14, 2017. Policy updated with literature review through November 2016; references 8-9, 17, 24, 28-29, 41, 50, 58, 60 added. Policy statements unchanged.
10/24/17	Policy moved to new format, no changes to policy statement.
04/01/18	Annual Review, approved March 13, 2018. Policy updated with literature review through November 2017; references 1, 3, 12-13, 47, 58-59, 62-63, 65-67, and 69-70 added. Modified list of conditions that are considered medically necessary. Added list of conditions that are considered investigational.
04/01/19	Annual Review, approved March 19, 2019. Policy updated with literature review through October 2018; references 41, 43-45, 76 added. Clarified medical necessity statement for non-healing diabetic wounds to include failure of "trial of 30 day" standard wound therapy.

Date	Comments
04/01/20	Annual Review, approved March 3, 2020. Policy updated with literature review through November 2019; references added. Policy statements unchanged. Approved March 10, 2020, delete policy. This policy will be deleted effective July 2, 2020 and replaced with InterQual criteria for dates of service on or after July 2, 2020.
06/10/20	Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.
07/31/20	Delete policy (2.01.505), approved July 14, 2020. This policy will be deleted effective August 1, 2020 and replaced with InterQual criteria for dates of service on or after August 1, 2020. Policy replaced with 2.01.04.
08/01/20	New policy (2.01.04), approved July 14, 2020. Policy replaces 2.01.505. Considered medically necessary for certain diagnosis, all else investigational.
08/07/20	Coding update. Removed HCPCS code A4575 from the policy.
04/01/21	Annual Review, approved March 2, 2021. Policy updated with literature review through November 14, 2020; references added. Policy statements unchanged. Added HCPC code A4575.
04/01/22	Policy renumbered from 2.01.04 Hyperbaric Oxygen Therapy to 2.01.505 Hyperbaric Oxygen Therapy, approved March 8, 2022. Policy updated with literature review through November 30, 2021; references added. Added central retinal artery occlusion to list of medically necessary conditions for HBOT use.
08/01/22	Interim Review, approved July 12, 2022. Changed the policy statement for HBOT for the treatment of idiopathic sudden sensorineural hearing loss from investigational to medically necessary.
10/01/22	Interim Review, approved September 13, 2022. Changed the policy statements for HBOT for the treatment of compromised skin grafts and flaps and necrotizing soft tissue infections from investigational to medically necessary.
09/01/23	Annual Review, approved August 21, 2023. Policy updated with literature review through April 28, 2023; References added. Changed the wording from "patient" to "individual" throughout the policy for standardization, otherwise, policy statements unchanged.
12/01/24	Annual Review, approved November 11, 2024. Policy updated with literature review through June 7, 2024. References added. Removed requirement that HBOT be initiated within 24 hours of CRAO symptom onset. Otherwise, policy statements unchanged. Added HCPCS code E0446 for topical hyperbaric oxygen therapy.

booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA).

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.