Hyperbaric Oxygen Therapy

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 won’t 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

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Systemic hyperbaric oxygen pressurization therapy</strong></td>
<td><strong>Systemic hyperbaric oxygen pressurization therapy may be considered medically necessary in the treatment of the following conditions:</strong></td>
</tr>
<tr>
<td></td>
<td>• Acute traumatic ischemia (eg, crush injuries, reperfusion injury, compartment syndrome)</td>
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<td></td>
<td>• Anemia from exceptional blood loss (profound): only when a blood transfusion is impossible or must be delayed</td>
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<td></td>
<td>• Carbon monoxide poisoning, acute</td>
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<td>• Cyanide poisoning, acute</td>
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<td></td>
<td>• Decompression sickness</td>
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<td>• Gas embolism, acute</td>
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<td>• Gas gangrene (ie, clostridial myonecrosis)</td>
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<td></td>
<td>• Non-healing diabetic wounds of the lower extremities in patients who meet the following 3 criteria:</td>
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<tr>
<td></td>
<td>o Patient has type 1 or type 2 diabetes and has a lower-extremity wound due to diabetes;</td>
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<td></td>
<td>o Patient has a wound classified as Wagner grade 3 or higher (see table below); and</td>
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<td></td>
<td>o Patient has no measurable signs of healing after 30 days of an adequate course of standard wound therapy;</td>
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<td></td>
<td>• Osteomyelitis, chronic refractory</td>
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<td></td>
<td>• Pre-and posttreatment for patients undergoing dental surgery (non-implant-related) of an irradiated jaw</td>
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<tr>
<td></td>
<td>• Soft tissue radiation necrosis (radiation enteritis, cystitis, proctitis) and osteoradionecrosis</td>
</tr>
<tr>
<td><strong>Hyperbaric oxygen pressurization</strong></td>
<td><strong>Hyperbaric oxygen pressurization is considered investigational in all other situations, including but not limited to, the treatment of the following conditions:</strong></td>
</tr>
<tr>
<td>Therapy</td>
<td>Investigational</td>
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<tr>
<td>• Acute arterial peripheral insufficiency;</td>
<td>• Acute ischemic stroke;</td>
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<tr>
<td>• Acute coronary syndromes and as an adjunct to coronary interventions, including but not limited to, percutaneous coronary interventions and cardiopulmonary bypass;</td>
<td>• Acute osteomyelitis;</td>
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<tr>
<td>• Acute surgical and traumatic wounds;</td>
<td>• Acute thermal burns;</td>
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<tr>
<td>• Acute ischemic stroke;</td>
<td>• Autism spectrum disorder;</td>
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<tr>
<td>• Acute osteomyelitis;</td>
<td>• Bell’s palsy;</td>
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<tr>
<td>• Acute surgical and traumatic wounds;</td>
<td>• Bisphosphonate-related osteonecrosis of the jaw;</td>
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<tr>
<td>• Acute thermal burns;</td>
<td>• Bone grafts;</td>
</tr>
<tr>
<td>• Autism spectrum disorder;</td>
<td>• Brown recluse spider bites;</td>
</tr>
<tr>
<td>• Bell’s palsy;</td>
<td>• Carbon tetrachloride poisoning, acute;</td>
</tr>
<tr>
<td>• Bisphosphonate-related osteonecrosis of the jaw;</td>
<td>• Cerebral edema, acute;</td>
</tr>
<tr>
<td>• Bone grafts;</td>
<td>• Cerebral palsy;</td>
</tr>
<tr>
<td>• Brown recluse spider bites;</td>
<td>• Cerebrovascular disease, acute (thrombotic or embolic) or chronic;</td>
</tr>
<tr>
<td>• Carbon tetrachloride poisoning, acute;</td>
<td>• Chronic arm lymphedema following radiotherapy for cancer;</td>
</tr>
<tr>
<td>• Cerebral edema, acute;</td>
<td>• Chronic wounds, other than those in patients with diabetes who meet the criteria specified in the medically necessary statement;</td>
</tr>
<tr>
<td>• Cerebral palsy;</td>
<td>• Compromised skin grafts or flaps;</td>
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<tr>
<td>• Cerebrovascular disease, acute (thrombotic or embolic) or chronic;</td>
<td>• Delayed-onset muscle soreness;</td>
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<tr>
<td>• Chronic arm lymphedema following radiotherapy for cancer;</td>
<td>• Demyelinating diseases (eg, multiple sclerosis, amyotrophic lateral sclerosis);</td>
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<tr>
<td>• Chronic wounds, other than those in patients with diabetes who meet the criteria specified in the medically necessary statement;</td>
<td>• Early treatment (beginning at completion of radiotherapy) to reduce adverse events of radiotherapy;</td>
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<tr>
<td>• Compromised skin grafts or flaps;</td>
<td>• Fibromyalgia; and</td>
</tr>
<tr>
<td>• Delayed-onset muscle soreness;</td>
<td>• Fracture healing;</td>
</tr>
<tr>
<td>• Demyelinating diseases (eg, multiple sclerosis, amyotrophic lateral sclerosis);</td>
<td>• Herpes zoster;</td>
</tr>
<tr>
<td>• Early treatment (beginning at completion of radiotherapy) to reduce adverse events of radiotherapy;</td>
<td>• Hydrogen sulfide poisoning;</td>
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<tr>
<td>• Fibromyalgia; and</td>
<td>• Idiopathic femoral neck necrosis;</td>
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<tr>
<td>• Fracture healing;</td>
<td>• Idiopathic sudden sensorineural hearing loss;</td>
</tr>
<tr>
<td>• Herpes zoster;</td>
<td>• In vitro fertilization;</td>
</tr>
<tr>
<td>• Hydrogen sulfide poisoning;</td>
<td>• Inflammatory bowel disease (Crohn disease or ulcerative colitis);</td>
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<tr>
<td>Therapy</td>
<td>Investigational</td>
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<td>------------------------------------------------------------------------</td>
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<tr>
<td>• Intra-abdominal and intracranial abscesses;</td>
<td>• Lepromatous leprosy;</td>
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<tr>
<td>• Meningitis;</td>
<td>• Mental illness (ie, posttraumatic stress disorder, generalized anxiety disorder or depression).</td>
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<tr>
<td>• Migraine;</td>
<td>• Motor dysfunction associated with stroke;</td>
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<tr>
<td>• Necrotizing soft tissue infections;</td>
<td>• Pseudomembranous colitis (antimicrobial agent-induced colitis);</td>
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<tr>
<td>• Pyoderma gangrenosum;</td>
<td>• Radiation myelitis;</td>
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<tr>
<td>• Radiation-induced injury in the head and neck, except as noted earlier in the medically necessary statement;</td>
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</tr>
<tr>
<td>• Refractory mycoses: mucormycosis, actinomycosis, conidiobolus coronato;</td>
<td>• Retinal artery insufficiency, acute;</td>
</tr>
<tr>
<td>• Retinopathy, adjunct to scleral buckling procedures in patients with sickle cell peripheral retinopathy and retinal detachment;</td>
<td>• Sickle cell crisis and/or hematuria;</td>
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<tr>
<td>• Sickle cell crisis and/or hematuria;</td>
<td>• Spinal cord injury;</td>
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<tr>
<td>• Spinal cord injury;</td>
<td>• Traumatic brain injury;</td>
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<tr>
<td>• Traumatic brain injury;</td>
<td>• Tumor sensitization for cancer treatments, including but not limited to, radiotherapy or chemotherapy;</td>
</tr>
<tr>
<td>• Vascular dementia</td>
<td>• Vascular dementia</td>
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</tbody>
</table>

**Topical hyperbaric oxygen therapy**

Topical hyperbaric oxygen therapy is considered investigational

**Topical Hyperbaric Oxygen**

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 hyperbaric oxygen may be performed in the office, clinic, or may be self-administered by the patient 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:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Lesion</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No open lesion</td>
</tr>
<tr>
<td>1</td>
<td>Superficial ulcer without penetration to deeper layers</td>
</tr>
<tr>
<td>2</td>
<td>Ulcer penetrates to tendon, bone, or joint</td>
</tr>
<tr>
<td>3</td>
<td>Lesion has penetrated deeper than grade 2 and there is abscess, osteomyelitis, pyarthrosis, plantar space abscess, or infection of the tendon and tendon sheaths</td>
</tr>
<tr>
<td>4</td>
<td>Wet or dry gangrene in the toes or forefoot</td>
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<tr>
<td>5</td>
<td>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</td>
</tr>
</tbody>
</table>

Following are recommended indications from the Undersea and Hyperbaric Medical Society’s (UHMS) 2014 Hyperbaric Oxygen Therapy Committee report on utilization of HBOT (13th edition):

- Acute thermal burn injury
- Air or gas embolism
- Arterial insufficiencies
- Carbon monoxide poisoning and carbon monoxide complicated by cyanide poisoning
- Clostridial myositis and myonecrosis (gas gangrene)
- Compromised grafts and flaps
- Crush injury, compartment syndrome, and other acute traumatic ischemias
- Decompression sickness
- Delayed radiation injury (soft tissue and bony necrosis)
- Idiopathic sudden sensorineural hearing loss.
- Intracranial abscess
• Necrotizing soft tissue infections
• Osteomyelitis (refractory)
• Severe anemia

Documentation Requirements
The patient’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:
  o Wagner ulcer grade
  o Prior therapy attempted

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>99183 Physician attendance and supervision of hyperbaric oxygen therapy, per session</td>
</tr>
<tr>
<td>HCPCS</td>
<td>G0277 Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval</td>
</tr>
</tbody>
</table>

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 (eg, antibiotics)

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 patient inside a hyperbaric chamber. HBOT can also be applied topically; ie, the body part to be treated is isolated (eg, 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.

Systemic HBOT

In systemic or large hyperbaric oxygen chambers, the patient 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 patient receives pure oxygen by mask, head tent, or endotracheal tube.
Topical HBOT

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 patients. 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.

Adverse Events

HBOT is a generally safe therapy, with an estimated adverse side effect rate of 0.4%.

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 HBOT, the evidence includes a systematic review, case series, and an RCT. Relevant outcomes are overall survival (OS), symptoms, change in disease status, and functional outcomes. The systematic review identified 3 RCTs including patients 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 patient populations and treatment regimens. The single small RCT (n=28) was not included in the review
and the uncontrolled studies do not provide sufficient data that topical HBOT is efficacious. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with chronic diabetic ulcers who receive systemic HBOT, the evidence includes RCTs and systematic reviews. 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. One of the 2 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 a meaningful improvement in the net health outcome.

For individuals with carbon monoxide poisoning who receive systemic HBOT, the evidence includes RCTs and a systematic review. 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 the effects of the technology on health outcomes.

However, clinical input obtained in 2010 and guidelines from the Undersea and Hyperbaric Medical Society and the 10th European Consensus Conference on Hyperbaric Medicine support HBOT for the treatment of acute carbon monoxide poisoning. Thus, based on clinical input and guideline support, this indication may be considered medically necessary.

For individuals with radionecrosis, osteoradionecrosis, or treatment of irradiated jaw who receive systemic HBOT, the evidence includes RCTs and a systematic review. 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 a meaningful improvement in the net health outcome.

For individuals with chronic refractory osteomyelitis who receive systemic HBOT, the evidence includes case series. 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 patients 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 the effects of the technology on health outcomes.

However, clinical input obtained in 2010 and Undersea and Hyperbaric Medical Society guidelines support HBOT for the treatment of chronic refractory osteomyelitis. Thus, based on clinical input and guideline support, this indication may be considered medically necessary.
For individuals with acute thermal burns who receive systemic HBOT, the evidence includes a systematic review of 2 RCTs. Relevant outcomes are OS, symptoms, and change in disease status. Only 2 RCTs were identified, and both were judged to have poor methodologic quality. Evidence from well-conducted controlled trials is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with acute surgical and traumatic wounds who receive systemic HBOT, the evidence includes RCTs, controlled nonrandomized studies, and systematic reviews. Relevant outcomes are OS, symptoms, change in disease status, and functional outcomes. There was considerable heterogeneity across the 4 RCTs identified (e.g., patient population, comparison group, treatment regimen, outcomes). This heterogeneity prevented pooling of trial findings and limits the ability to conclude the impact of HBOT on health outcomes for patients with acute surgical and traumatic wounds. Additional evidence from high-quality RCTs is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with bisphosphonate-related osteonecrosis of the jaw who receive systemic HBOT, the evidence includes an RCT. Relevant outcomes are symptoms and change in disease status. The RCT was unblinded and reported initial benefits at 3-month follow-up; however, there were no significant benefits of HBOT for most health outcomes compared with standard care in the long-term (6 months to 2 years). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with necrotizing soft tissue infections who receive systemic HBOT, the evidence includes systematic reviews and a retrospective cohort study. Relevant outcomes are OS, symptoms, and change in disease status. A Cochrane review did not identify any RCTs. Another systematic review identified a retrospective cohort study, which did not find better outcomes after HBOT than after standard care without HBOT in patients with necrotizing soft tissue infections. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with acute coronary syndrome who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are OS, symptoms, change in disease status, and functional outcomes. A Cochrane review identified 6 RCTs. There were 2 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 the effects of the technology on health outcomes.

For individuals with acute ischemic stroke who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are OS, symptoms, change in disease status, and functional outcomes. Cochrane reviewers could only pool data for a single outcome
(mortality at 3-6 months), and for that outcome, there was no significant difference between active and sham HBOT treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with motor dysfunction associated with stroke who receive systemic HBOT, the evidence includes an RCT. Relevant outcomes are symptoms and functional outcomes. The RCT, which used a crossover design, found better outcomes with HBOT at 2 months than with delayed treatment. However, the trial had a number of methodologic limitations (eg, 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 the effects of the technology on health outcomes.

For individuals with Bell’s palsy who receive systemic HBOT, the evidence includes a systematic review. 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 the effects of the technology on health outcomes.

For individuals with traumatic brain injury who receive systemic HBOT, the evidence includes RCTs and systematic reviews. Relevant outcomes are OS, symptoms, change in disease status, and functional outcomes. RCTs were heterogenous regarding intervention protocols, patient populations, and outcomes reported. Multiple RCTs of US military service members showed no statistical difference in outcomes between HBOT groups and those that received sham treatment. Systematic reviews conducted pooled analyses only on a minority of the published RCTs, and these findings were inconsistent. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with inflammatory bowel disease who receive systemic HBOT, the evidence includes an RCT, observational studies, and a systematic review. Relevant outcomes are symptoms, change in disease status and functional outcomes. One small RCT has been published, and this trial did not find a significant improvement in health outcomes when HBOT was added to standard medical therapy. 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 the effects of the technology on health outcomes.

A Cochrane review of RCTs had mixed findings from studies that included individuals with tinnitus. Some outcomes (ie, 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 patients enrolled in the studies. A subsequent systematic review had similarly limited conclusions due to
the inclusion of non-randomized studies. One RCT included in this review included patients with idiopathic sudden sensorineural hearing loss and found no differences in HBOT treatment compared with steroid injections in mean hearing thresholds at 0.25, 0.5, 1, and 4 kHz; however, a significant difference was detected at the 2-kHz level. Nonrandomized studies of HBOT used as adjunctive therapy did not support incremental value, although 1 systematic review evaluated HBOT along with steroid therapy and found benefit specifically for those with severe-to-profound idiopathic sudden sensorineural hearing loss. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with delayed-onset muscle soreness who receive systemic HBOT, the evidence includes RCTs and a systematic review. 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 (eg, swelling). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with autism spectrum disorder who receive systemic HBOT, the evidence includes an RCT and a systematic review. 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 the effects of the technology on health outcomes.

For individuals with cerebral palsy who receive systemic HBOT, the evidence includes 2 RCTs and an observational study. 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 the effects of the technology on health outcomes.

For individuals with vascular dementia who receive systemic HBOT, the evidence includes an RCT and a systematic review. 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 the effects of the technology on health outcomes.

For individuals with radiotherapy adverse events who receive systemic HBOT, the evidence includes RCTs, nonrandomized comparator trials, case series, and systematic reviews. Relevant outcomes are symptoms and functional outcomes. Two systematic reviews were identified, but pooled analyses were not possible due to heterogeneity in treatment regimens and outcomes measured. One systematic review concluded that more RCTs would be needed. The 2 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. An observational study for dry mouth (xerostomia) caused by radiotherapy found some benefit to HBOT. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with idiopathic femoral neck necrosis who receive systemic HBOT, the evidence includes an RCT. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCT, which had a small sample, only reported short-term (ie, 6-week) outcomes. Larger well-conducted RCTs reporting longer-term outcomes are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with a migraine who receive systemic HBOT, the evidence includes RCTs and a systematic review. 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 3 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 the effects of the technology on health outcomes.

For individuals with herpes zoster who receive systemic HBOT, the evidence includes an RCT. Relevant outcomes are symptoms and change in disease status. The RCT was unblinded and only reported short-term (ie, 6-week) outcomes. Additional well-conducted RCTs with longer follow-up are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with fibromyalgia who receive systemic HBOT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Only 2 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 (eg, 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 the effects of the technology on health outcomes.

For individuals with multiple sclerosis who receive systemic HBOT, the evidence includes RCTs and a systematic review. 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 patients with multiple sclerosis were treated with HBOT versus a comparator intervention. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals with cancer and are undergoing chemotherapy who receive systemic HBOT, the evidence includes an RCT and a systematic review. Relevant outcomes are OS and change in disease status. While the systematic review reported improvements in tumor control in patients with head and neck cancer who received HBOT, the adverse events accompanying the treatment (eg, radiation tissue injury, seizures) were significant. The single RCT did not find a significant difference in survival for cancer patients who received HBOT before chemotherapy compared with usual care. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

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

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
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<tr>
<td>NCT02089594</td>
<td>Hyperbaric Oxygen Therapy Treatment of Chronic Mild Traumatic Brain Injury (mTBI)/Persistent Post-Concussion Syndrome (PCCS)</td>
<td>59</td>
<td>Mar 2019</td>
</tr>
<tr>
<td>NCT03325959</td>
<td>Hyperbaric Oxygen versus Standard Pharmaceutical Therapies for Fibromyalgia Syndrome - Prospective, Randomized, Crossover Clinical Trial</td>
<td>70</td>
<td>Nov 2019</td>
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<tr>
<td>NCT00596180</td>
<td>Hyperbaric Oxygen Therapy and SPECT Brain Imaging in Carbon Monoxide Poisoning</td>
<td>40</td>
<td>Dec 2019</td>
</tr>
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<td>NCT01002209</td>
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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.

In response to requests, input was received from 6 physician specialty societies and 5 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

Diabetic Foot Conditions

Undersea and Hyperbaric Medical Society

In 2015, the Undersea and Hyperbaric Medical Society (UHMS) published guidelines on the use of hyperbaric oxygen therapy (HBOT) for treating diabetic foot ulcers. This guideline is scheduled for a revision in 2018. 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.

Infectious Disease Society of America

In 2012, the Infectious Disease Society of America published guidelines on the diagnosis and treatment of diabetic foot infections. The guidelines stated that “for selected diabetic foot wounds that are slow to heal, clinicians might consider using hyperbaric oxygen therapy (strength of evidence: strong; quality of evidence: moderate).”

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. According to the guidelines, for diabetic foot ulcers that fail to demonstrate improvement (>50% wound area reduction) after a minimum of 4 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 4 to 6 weeks of conservative management, HBOT is suggested (grade 2B).

Other Conditions

Undersea and Hyperbaric Medical Society

The 2014 UHMS hyperbaric oxygen therapy indications committee report included the following indications as recommended:

- Acute Thermal Burn Injury
- Air or Gas Embolism
- Arterial Insufficiencies
- Carbon Monoxide Poisoning and carbon monoxide complicated by cyanide poisoning
- Clostridial Myositis and Myonecrosis (Gas Gangrene)
- Compromised Grafts and Flaps
- Crush Injury, Compartment Syndrome and Other Acute Traumatic Ischemias
- Decompression Sickness
- Delayed Radiation Injury (Soft Tissue and Bony Necrosis)
- Idiopathic Sudden Sensorineural Hearing Loss.
- Intracranial Abscess
- Necrotizing Soft Tissue Infections
- Osteomyelitis (Refractory)
- Severe Anemia

The UHMS has also published position statements that concluded there was insufficient evidence to recommend topical HBOT for chronic wounds (2005), multiple sclerosis, and autism spectrum disorder (2009).

American Academy of Otolaryngology-Head and Neck Surgery

In 2018, the American Academy of Otolaryngology-Head and Neck Surgery updated clinical guidelines on treatment of sudden hearing loss. 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 SSNH."

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

**Medicare National Coverage**

In 2003, 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:

- 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:
  - Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
  - Patient has a wound classified as Wagner grade III or higher; and
  - Patient 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 patients 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, débridement 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 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.”

Regulatory Status

Since 1979, the 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. 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.

References


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## History

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<td>08/0720</td>
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
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