Hyperbaric Oxygen Therapy (HBOT)

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<th>Type:</th>
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<td>Medical Necessity and Investigational / Experimental</td>
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<th>Original Policy Date:</th>
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Description

Hyperbaric Oxygen Therapy (HBOT) is a technique of delivering higher pressures of oxygen to the tissues. Two methods of administration, topical and systemic, are available. Topical hyperbaric oxygen 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. Topical hyperbaric oxygen 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 oxygen therapy has been investigated predominantly in the treatment of chronic wounds (specifically foot wounds) in diabetic patients.

In systemic or large chamber hyperbaric oxygen, the patient is entirely enclosed in a pressure chamber and breathes oxygen at a pressure greater than 1 atmosphere (the pressure of O₂ at sea level). Thus, this technique relies on the systemic circulation to deliver highly oxygenated blood to the target site, typically a wound. Systemic hyperbaric oxygen therapy is used to treat wounds as well as systemic illnesses such as air or gas embolism, carbon monoxide poisoning, and clostridial gas gangrene. Treatment may be carried out either in a monoplace chamber pressurized with pure oxygen or in a larger, multi-place chamber pressurized with compressed air, in which case the patient receives pure oxygen by mask, head tent, or endotracheal tube.
Policy

Topical hyperbaric oxygen therapy is considered **investigational**.

Systemic hyperbaric oxygen therapy is considered **medically necessary** in the treatment of **any** of the following conditions:

- Acute gas or air embolism
- Acute traumatic ischemia
- Acute Cyanide Poisoning
- Carbon monoxide poisoning
- Chronic non-healing wounds in patients who meet all of the following criteria:
  - A lower extremity wound
  - A wound classified as Wagner* grade 3 or higher (Refer to Table 1)
  - No measurable signs of healing after 30 days of an adequate course of standard wound therapy
  - Type I or type II diabetes
- Decompression sickness
- Gas gangrene (i.e., clostridial myositis and myonecrosis)
- Pre- and post-treatment for patients undergoing dental surgery (non-implant related) of an irradiated jaw
- Profound anemia with exceptional blood loss only when blood transfusion is impossible or must be delayed
- Soft-tissue radiation necrosis, osteoradionecrosis, and chronic or delayed radiation enteritis, cystitis, or proctitis

Table 1 *Wagner classification system of wounds is defined as follows:

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<th>Grade</th>
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<tr>
<td>0</td>
<td>No open lesion</td>
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<tr>
<td>1</td>
<td>Superficial ulcer without penetration to deeper layers</td>
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<tr>
<td>2</td>
<td>Ulcer penetrates to tendon, bone, or joint</td>
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<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>
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<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 percentage that no local procedures are possible and amputation (at least at the below the knee level) is indicated</td>
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The continuation of systemic hyperbaric oxygen treatment is considered **not medically necessary** if the wound fails to show measurable signs of healing within 30 days of therapy.
Systemic hyperbaric oxygen therapy is considered **investigational** or *not medically necessary* for treatment of the following conditions (not an all inclusive list) because there is insufficient evidence in the medical literature to establish that systemic HBOT is more effective than conventional therapies:

- Acute carbon tetrachloride poisoning
- Acute cerebral edema
- Acute cerebrovascular disease, (thrombotic or embolic) or chronic
- Acute coronary syndromes and as adjunct to coronary interventions, including but not limited to percutaneous coronary interventions and cardiopulmonary bypass
- Acute renal arterial insufficiency
- Acute thermal burns
- Acute, non-traumatic peripheral arterial insufficiency (e.g., thrombotic, or embolic)
- Autism*
- Bone grafts
- Brown recluse spider bites
- Cerebral Palsy
- Chronic refractory osteomyelitis and acute osteomyelitis, refractory to standard medical management
- Compromised skin grafts or flaps
- Demyelinating diseases, (e.g., multiple sclerosis, amyotrophic lateral sclerosis)
- Fracture healing
- Hydrogen sulfide poisoning
- Idiopathic sudden sensorineural hearing loss
- Intra-abdominal abscess
- Intracranial abscess
- Lepromatous abscess
- Leprosy
- Lyme Disease*
- Malignant Otitis Externa*
- Meningitis
- Migraine
- Necrotizing soft-tissue infections
- Organ transplantation and/or storage*
- Pseudomembranous colitis (antimicrobial agent-induced colitis)
- Pyoderma gangrenosum
- Radiation myelitis
- Refractory mycoses: mucormycosis, actinomycosis, canidiobolus coronato
- Retinopathy, adjunct to scleral buckling procedures in patients with sickle cell peripheral retinopathy and retinal detachment
- Senility, dementia, or cognitive impairment*
- Severe or refractory Crohn’s disease
- Sickle cell crisis and/or hematuria
- Soft tissue injury (i.e., delayed onset muscle soreness, closed soft tissue injury, sprains)
• Spinal cord injury
• Traumatic brain injury
• Tumor sensitization for cancer treatments, including but not limited to radiotherapy or chemotherapy

Rationale

Topical Hyperbaric Oxygen

Due to their different methods of delivery, topical and systemic hyperbaric oxygen are distinct technologies such that the outcomes associated with systemic hyperbaric oxygen therapy cannot be compared to one another. Topical oxygen commonly referred to as topical hyperbaric oxygen therapy is administered to the open wound in small limb-encasing devices. Topical therapy has been predominantly investigated in chronic, small wounds (i.e., diabetic foot ulcers) with the intent of increasing oxygen levels to the surface area. Topical hyperbaric oxygen may be performed in the office, clinic, or 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. Examples of topical HBOT devices are TOPOX portable hyperbaric oxygen extremity and sacral chambers (Jersey City, NJ), and Oxyboot and Oxyhealer from GWR Medical, L.L.P. (Chadds Ford, PA).

There is minimal published literature regarding topical hyperbaric oxygen therapy. In 1984, Heng and colleagues published a controlled study of topical hyperbaric oxygen therapy in 6 patients with 27 ulcers compared to no treatment in 5 patients with 10 ulcers. Although a greater improvement was noted in the treated group, the results were calculated according to the number of ulcers rather than based on individual patients. Leslie and colleagues (1988) reported on a trial that randomized 18 patients with diabetic foot ulcers to receive topical hyperbaric oxygen therapy plus standard wound care or standard wound care alone. Changes in ulcer size and depth did not differ between the 2 groups. Other studies consist of anecdotal reports or uncontrolled case series.

The Undersea and Hyperbaric Medical Society (2005) issued a position statement on topical hyperbaric oxygen therapy and advised that "topical oxygen" should not be termed "hyperbaric oxygen" since doing so either intentionally or unintentionally suggests that oxygen treatment is equivalent or even identical to hyperbaric oxygen. Namely, their physiology, biochemistry, delivery, and efficiencies of entry to the wound are different. "The application of topical oxygen cannot be recommended outside of a clinical trial at this time based on the volume and quality of scientific supporting evidence available, nor does the Society recommend third party payer reimbursement." Also, topical oxygen application has not been subjected to the same intense scientific scrutiny to which systemic hyperbaric oxygen has been held.

Therefore, topical hyperbaric oxygen therapy is considered investigational in all cases because there is not adequate published data from controlled trials to permit scientific conclusions.
Systemic Hyperbaric Oxygen

Systemic Hyperbaric oxygen administration is a modality in which the whole body is exposed to pure oxygen gas, within an enclosed clear, acrylic chamber, under increased atmospheric pressure. The technique relies on systemic circulation to deliver highly oxygenated blood to the target tissues. The treatment increases the available oxygen to the body 10-20 times and saturates the blood tissues with oxygen. Most hyperbaric chambers are monoplace or single person clear chambers allowing for continuous visual contact. Multi-place chambers are larger and allow treatment of more than one patient at a given time (i.e., treatment of an entire family exposed to carbon monoxide poisoning or for an Intensive Care unit (ICU) patient requiring continuous nursing treatment). The chamber is compressed with air, and a face mask or a head tent delivers oxygen. The number and duration of treatment sessions, and atmospheric pressure during treatment may vary depending on the severity of the condition and the procedures developed by individual hospitals and clinics. In general, treatment may range from less than 1 week to several months' duration, the average being 2 to 4 weeks. The literature advises that HBOT however, should not be considered a replacement for standard therapeutic measures.

Hyperbaric Oxygen Therapy (HBO or HBOT) is safe with relatively few complications and side effects. The most common side effects include middle ear barotrauma, or "ear squeeze," and sinus barotrauma or "sinus squeeze." Slow compression rates with frequent stops and treatment with decongestant nasal spray prior to HBOT can prevent or regulate the problems. Less common side effects are oxygen or pulmonary toxicity, claustrophobia, visual refractive changes, seizures and decompression sickness.

Relative contraindications to the use of HBOT include prior chest surgery, lung disease, viral infections, recent middle ear surgery, optic neuritis, seizure disorders, high fever, and congenital spherocytosis and claustrophobia. Absolute contraindications to HBOT include untreated pneumothorax, concurrent administration of disulfuram (Antabuse); concurrent administration of the antineoplastic agents' doxorubicin and cisplatinum; and administration to premature infants (due to the risk of retrolental fibroplasias).

Systemic Hyperbaric Oxygenation (HBO₂) services must comply with the following guidelines which are consistent with the United States (U.S.) Food and Drug Administration (FDA) and the Undersea and Hyperbaric Medical Society criteria:

- Patient must breathe 100% oxygen intermittently or continuously while the pressure of the treatment chamber is increased above one Atmosphere Absolute (ATM ABS)
- Systemic hyperbaric oxygen pressurization should be at least 1.4 atmospheres absolute (ATM ABS)

Anything less than 100% oxygen at 1.4 ATM ABS or exposing isolated parts of the body to 100% oxygen does not constitute systemic hyperbaric oxygen therapy.

The Undersea and Hyperbaric Medical Society's 1999 and 2003 Hyperbaric Oxygen Therapy Committee Report recommends utilization review of need for continued HBO₂ at the following treatment thresholds:

- Arterial gas embolism, acute - 10 treatments
- Carbon monoxide poisoning - five treatments
- Chronic non-healing wounds - 30 treatments (one or two treatments daily)
• Decompression Sickness - ten treatments
• Gas gangrene - ten treatments
• Acute Traumatic Ischemia - six days of treatment (up to three treatments daily)
• Radiation tissue injury, chronic - 60 treatments

A number of technology assessments, societies and organizations have systematically reviewed the evidence supporting the use of hyperbaric oxygen (HBO) for each of the indications for which it has been used. These include, but are not limited to Blue Cross Blue Shield Technology Evaluation Center (TEC) assessments, the Cochrane Collaboration, the Agency for Healthcare Research and Quality (AHRQ), the Undersea and Hyperbaric Medical Society Committee (UHMSC) guidelines, the American College of Hyperbaric Medicine (ACHM) and the Alberta Heritage Foundation for Medical Research (AHFMR).

The Undersea and Hyperbaric Medical Society (UHMS) published new guidelines in 2003. The UHMS's Hyperbaric Oxygen Therapy Committee continues to consider HBO to be appropriate for these conditions:
• Air or gas embolism
• Carbon monoxide poisoning and carbon monoxide complicated by cyanide poisoning
• Clostridal myositis and myonecrosis (gas gangrene)
• Crush injury, compartment syndrome and other acute traumatic ischemias
• Decompression sickness
• Enhancement of healing in selected problem wounds
• Exceptional blood loss (anemia)
• Intracranial abscess
• Necrotizing soft tissue infections
• Osteomyelitis (refractory)
• Delayed radiation injury (soft tissue and bony necrosis)
• Skin grafts and flaps (compromised)
• Thermal burns

In contrast to the Undersea and Hyperbaric Medical Society guidelines, the Blue Cross Blue Shield Association (BCBSA) TEC Assessments concluded that there was inadequate literature to validate the effectiveness of systemic hyperbaric oxygen for the following conditions:
• Compromised skin grafts
• Acute thermal burns
• Chronic refractory osteomyelitis
• Necrotizing soft tissue infections
• Brown recluse spider bites

TEC Assessments (1999) offered the following conclusions regarding the above statement and also included study on the use of HBOT for perineal Crohn's disease, and spinal cord or brain injury not addressed by the Undersea and Hyperbaric Medical Society guidelines:
• Compromised skin grafts:
  o Only 1 controlled trial studying the effects of systemic hyperbaric oxygen in the treatment of skin grafts was identified. Although this 1967 randomized study of 48
patients reported increased graft survival in the HBO-treated group, the sample included all patients undergoing skin grafting. Therefore, the success of HBO in treating the most clinically relevant subgroup of those with compromised skin grafts is unknown

- The Assessment concluded that there was insufficient evidence to permit conclusions.

- Acute thermal burns:
  - The largest controlled study of this application was a 1997 study that randomized 125 patients with acute thermal burns to systemic hyperbaric oxygen or a control group. The authors found no difference in the number of necessary surgical procedures between HBO-treated and non-treated patients, and there was no difference in hospital length of stay. (This 1997 study was not reviewed as part of the 1996 Undersea and Hyperbaric Society guidelines)
  - The Assessment concluded that the evidence did not support that HBO is beneficial in the treatment of severe acute thermal burns

- Chronic refractory osteomyelitis:
  - Justification for the use of HBO in chronic osteomyelitis has been based primarily on case series and few have instituted sufficient study controls to make that determination. There are few contemporary studies, and the introduction of more effective antibiotic therapies, advances in the method and extent of surgical debridement, more sophisticated wound coverage procedures, and improved microvascular repair in the last decade may limit the application of these earlier results to current therapy
  - The Assessment concluded that there were inadequate data to permit conclusions.

- Necrotizing soft tissue infections:
  - Justification for the use of HBO in necrotizing infections has been based largely on animal studies, case reports, and retrospective reviews. Improved patient outcomes have been attributed to the adjunctive use of HBO, although these open series have failed to include a non-HBO-treated control group
  - The Assessment concluded that there were inadequate data to permit conclusions.

- Traumatic Brain Injury
  - Hyperbaric oxygen therapy has been advocated as a method of improving neurologic recovery after ischemia, however, studies in both animals and humans have yielded inconsistent results
  - The TEC Assessment focused on 2 randomized controlled studies, both of which suggested that the functional outcomes of survivors were not improved with the use of HBO
  - The Assessment concluded that there was insufficient evidence to permit conclusions.

- Spinal Cord Injury
  - The use of HBO therapy in patients with spinal cord injury is based in part on the fact that spinal cord impairment is a frequent complication of decompression sickness and that HBO is a definitive treatment of decompression sickness. The TEC Assessment focused on the use of HBO as a treatment of spinal cord injury unrelated to decompression sickness
The available evidence was limited to experimental animal models and small uncontrolled human series.

The Assessment concluded that there was insufficient evidence to permit conclusions.

Severe or refractory Crohn’s disease

Severe or refractory perineal wounds in Crohn's disease resemble chronic wounds, which are frequently complicated by local tissue hypoxia and anaerobic bacteria. The presence of tissue hypoxia is the basis of HBO therapy.

The available evidence consisted of case reports, small uncontrolled case series, and 1 case-controlled report that observed intermediate outcomes only.

The Assessment concluded that there was insufficient evidence to permit conclusions.

Recluse brown spider bites

A small percentage of brown recluse spider bites produce large, slow-healing ulcerative lesions. HBO therapy has been suggested as a potential therapy, both to decrease the potency of the brown spider venom and to promote wound healing by increasing tissue oxygen tension.

The available evidence was limited to experimental animal models and small uncontrolled human series.

The Assessment concluded that there was insufficient evidence to permit conclusions.

Alberta Heritage Foundation for Medical Research (AHFMR)

The Alberta Heritage Foundation for Medical Research (Hailey, 2003) conducted an evidence review and concluded that use of HBOT is not supported for a number of conditions, including non-diabetic wounds, multiple sclerosis, cerebral palsy, decubitus ulcers, necrotizing arachnidism, actinomycosis, cardiovascular conditions, Bell's palsy, cluster and migraine headaches, Legg-Calve Perthes disease, Crohn's disease, osteoporosis, cancer, head trauma, cognitive impairment, senile dementia, glaucoma, keratoendotheliosis, Human Immunodeficiency Virus (HIV) infection, facial neuritis, and nonunion of fractures.

Medically Necessary Conditions

Acute Cyanide Poisoning

The use of HBOT has been proven as adjunctive therapy after administration of the antidote sodium thiosulfate. When used in combination HBOT provides an alternate pathway to the transport of oxygen to the tissues thereby increasing serum dissolved oxygen levels adequate for life, and bypassing bound hemoglobin.

Acute Gas or Air Embolism

The safety and efficacy of HBOT as primary therapy for the treatment of air or gas embolism (obstruction of a blood vessel by a gas bubble), has been demonstrated in evidenced-based, peer reviewed journals, textbooks and the Undersea and Hyperbaric Medical Society guidelines as well as the American College of Hyperbaric Medicine (ACHM).

Acute Traumatic Ischemia

Acute traumatic ischemia is characterized by a vicious circle of ischemia, hypoxia, edema, disturbed microcirculation, and secondary ischemia in the border area of the tissue affected by
the primary trauma. In hypoxic tissues mechanisms of infection control and healing are impaired so that the risk of infection and wound healing problems are definitely higher than after other kinds of injuries. Restoration of perfusion can lead to reperfusion injury. Hyperbaric oxygen ameliorates the effects of acute traumatic ischemia through four mechanisms: hyperoxygenation, vasoconstriction, and influence on reperfusion and host factors. Surgical intervention and shock management along with early adjuvant hyperbaric oxygen therapy (HBOT) administration can prevent large expanses of ischemic necrosis, minimize the frequency and extent of amputations, reduce edema, control infection, support healing, and prevent reperfusion injury.

**Carbon Monoxide Poisoning**

Scheinkestel et al. (1999) conducted a double-blind, randomized controlled trial comparing HBO to normobaric oxygen in patients with carbon monoxide poisoning. The authors reported that HBO did not benefit patient outcomes of neuropsychological performance when HBO therapy was completed and at 1-month follow-up. In addition, a Cochrane review of seven randomized controlled trials concluded the available evidence is insufficient to determine whether adverse neurologic outcomes are reduced with HBO therapy.

The American College of Emergency Physicians recently published its clinical policy on critical issues in carbon monoxide poisoning. This clinical policy indicated that 1) HBO is a therapeutic option for carbon monoxide-poisoned patients; however, its use cannot be mandated; and 2) no clinical variables, including carboxyhemoglobin levels identify a subgroup of carbon monoxide-poisoned patients for whom HBO is most likely to provide benefit or cause harm.

Proponents for use of HBO in this situation frequently cite the other blinded trial by Weaver, which showed improvements in a composite cognitive outcome score for those treated with hyperbaric compared to normobaric oxygen. However, the authors note that the T-scores for the neuropsychological tests did not differ significantly between the treatment groups (p=0.31); thus raising questions about the impact of treatment. In light of the data from randomized trials, questions about the role of HBO in the treatment of carbon monoxide poisoning persist.

However, while evidence for the treatment of acute carbon monoxide poisoning with hyperbaric oxygen pressurization has failed to demonstrate improved health outcomes, this technology has been accepted into medical practice as a standard medical therapy for the treatment of carbon monoxide poisoning. HBOT is also recommended by the Undersea and Hyperbaric Medical Society Guidelines and the American College of Hyperbaric Medicine.

**Chronic non-healing diabetic wounds of the lower extremities**

A Cochrane analysis of HBO treatment for chronic wounds was conducted by Kranke and colleagues (2005). The authors reported finding no evidence to demonstrate benefits with use of HBO for arterial, venous, pressure ulcers, wounds or other pathologies due to limited trial data. However, they concluded that HBO significantly reduced the risk of major amputations from diabetic ulcers based on analysis from 5 trials totaling 118 patients.

The Ontario Health Technology Advisory Committee (OHTAC) in 2005 advised that the evidence published to date is uncertain for the use of HBOT for patients with diabetic non-healing ulcers. The committee recognized that treatments may be useful for severe infections or
for those that have not adequately responded to therapy, despite correcting for all amenable local and systemic adverse factors.

An AHRQ systematic review of the literature done by Wang et al.(2003) identified studies from technology assessment reports on HBO and a MEDLINE search from mid-1998 to August 2001 that evaluated the use of HBO for wound care and reported clinical outcomes. Results suggested "that HBO may be beneficial as an adjunctive therapy for chronic non-healing diabetic wounds, compromised skin grafts, osteoradionecrosis, soft tissue radionecrosis, and gas gangrene compared with standard wound care alone. Serious adverse events associated with HBO included seizures and pressure-related traumas, such as pneumothorax."

The evidence for treatment of diabetic wounds/ulcers of the lower extremity with HBOT is limited. However, HBOT as adjunctive therapy appears to have evolved into an accepted practice for patients with diabetic wounds Wagner grade III or higher that are refractory to conventional wound care, aggressive diabetes management and surgical interventions. Wounds should be evaluated at least every 30 days during administration of HBOT. Continued treatment with HBOT is not considered medically necessary if measurable signs of healing have not been demonstrated within any 30 day period.

Decompression Sickness

Decompression sickness is a condition that develops in divers subjected to rapid reduction of air pressure after coming to the surface following exposure to compressed air. The safety and effectiveness of HBOT has been demonstrated in many evidence based, peer reviewed journals and consensus guidelines and is felt to be the standard of care in the primary treatment of decompression sickness.

Gas Gangrene

Gas gangrene is a condition most often caused by bacteria called Clostridium perfringens. However, it also can be caused by Group A streptococcus. Staphylococcus aureus and Vibrio vulnificus can cause similar infections. Under low oxygen (anaerobic) conditions, Clostridium produces toxins that cause tissue death and related symptoms. The scientific literature has supported the adjunctive use of HBOT in the treatment of diabetic foot wounds infected with clostridial myonecrosis (i.e., gas gangrene) that are unresponsive to aggressive standard wound care, glucose control and debridement.

Pre-and post-treatment undergoing dental surgery for an irradiated jaw

A 2008 Cochrane review by Esposito reviewed the use of HBO in patients requiring dental implants. The authors identified 1 randomized trial involving 26 patients. The authors concluded that despite the limited amount of clinical research available, it appears that HBO therapy in irradiated patients requiring dental implants may not offer any appreciable clinical benefits. They indicate that there is a definite need for more Randomized Controlled Trials (RCT) to ascertain the effectiveness of HBO in irradiated patients requiring dental implants.

In summary, given the longstanding use of this technology, the existing literature base, the Cochrane review noted above, and the ongoing favorable publications, the use of HBO for treatment of soft-tissue and bone radiation necrosis and for pre- and post-treatment of dental surgery (non-implant related) in an irradiated jaw is considered medically necessary.
Profound Anemia

Evidence supporting the use of HBOT for exceptional blood loss when transfusion is not an option is very limited. Hart et al. (1987) included 26 patients in a review of the experience with HBOT in the treatment of exceptional blood loss anemia. Six patients died who arrived for treatment in decorticate or decerebrate neurologic states and had lower hematocrits and hemoglobins than the survivors. While there were limitations to the study, the authors reported that HBOT is a valuable adjunct to the treatment of acute blood loss anemias. Van Meter et al. (2005) conducted a systematic review in the use of HBOT in the treatment of severe anemia. Positive results were reported by the authors from nine human studies included in the review. Although the evidence is somewhat limited supporting HBOT for profound anemia it seems that it has emerged into an acceptable treatment option.

Radionecrosis and Osteoradionecrosis and Delayed Radiation Enteritis, Cystitis, or Proctitis

In an earlier review of this topic, Feldmeier (2002) commented on a review of 74 publications representing results of applying HBO in the treatment or prevention of radiation injuries. The authors appraised studies in an evidence-based fashion. All but 7 of the publications report a positive result when HBO was delivered as treatment for or prevention of delayed radiation injury. The authors also noted that these results were impressive in the context of alternative interventions such as surgery of irradiated tissue. Based on this review, the authors concluded that HBO is recommended for delayed radiation injuries for soft tissue and bony injuries of most sites. They also note an increasing body of evidence for HBO in radiation-induced necrosis of the brain, and comment that for other radiation-induced neurological injuries, additional study is required.

In the Cochrane review of randomized trials (2005), Bennett concludes that "these small trials suggest that for people with Late Radiation Tissue Injury (LRTI) affecting the head, neck, anus, and rectum, HBOT is associated with improved outcome. HBOT also appears to reduce the chance of osteoradionecrosis following tooth extraction in an irradiated field. There was no such evidence of any important clinical effect on neurological tissues. The application of HBOT to selected patients and tissues may be justified." The authors also noted that intermittent application of HBO is the only intervention that has been shown to increase the number of blood vessels in irradiated tissue; as noted, this work was first reported in the late 1980's by Marx.

Results for use of (HBOT) for this indication continue to be published. Given the limited number of options available to patients with these late effects of radiation therapy, results of cohort studies as well as randomized trials can be used in evaluating the clinical evidence. Hampson and colleagues (2007) reported results on a series of 65 patients with radiation enteritis/proctitis and 94 patients with cystitis at one institution. In this series, response was better in patients receiving 30 or more total treatments as compared with fewer treatments. In a review of management of radiation-induced necrosis, Delanian comments on the role of hyperbaric oxygen therapy as part of the "vascular" treatment of this condition.
Investigational and/or Not Medically Necessary Conditions

Acute Coronary Syndromes as an Adjunct to Coronary Interventions (including Percutaneous Coronary Intervention and Cardiopulmonary Bypass)

A Cochrane systematic review was conducted by Bennett et al. (2005) of four studies that reviewed the effect of using HBOT as an adjunct to standard Acute Coronary Syndrome (ACS) regimes versus stand alone standards of care. The reviewers concluded that there is limited evidence that HBOT reduces the risk of major adverse coronary events, impacts cardiac dysrhythmia, or decreases the time intervals of ischemic pain during these events. These studies were small in number and population size and had methodological and reporting inadequacies noted. The authors reported that they could not recommend the use of HBOT as an adjunct to standard ACS therapy regimens within this population.

Sharifi and colleagues (2004) reported on a trial that randomized 69 patients with unstable angina or acute myocardial infarction to receive or not receive HBO after a Percutaneous Coronary Intervention (PCI). The rationale behind this investigation was that HBO therapy might accelerate the healing of the microtrauma associated with a PCI and thus ultimately reduce the restenosis rate. The 24 patients randomized to the HBO group reported only 1 adverse event (death, myocardial infarction, coronary artery bypass, or revascularization of target lesion), compared to 13 in the 37 control patients. However, this study lacks adequate detail to permit scientific conclusions. For example, details of the type of percutaneous coronary intervention (PCI) performed, i.e., whether a drug-eluting stent was used, were not provided. In addition, a Cochrane review of 4 trials with a total of 462 patients concluded there were no significant benefits for patients with acute coronary syndromes receiving HBO.

In an Randomized Controlled Trial (RCT) of 64 patients, Alex and colleagues (2005) concluded both neuropsychometric dysfunction and inflammatory response can be reduced post-cardiopulmonary bypass when HBO pretreatment is given. However, the authors noted additional studies were needed to evaluate HBO for this indication. Therefore, acute coronary syndromes as an adjunct to coronary interventions, including but not limited to percutaneous coronary interventions and cardiopulmonary bypass is considered investigational.

Acute (non-traumatic) Peripheral Arterial Insufficiency

Medicare has long listed acute peripheral arterial insufficiency as a medically necessary indication. However, no clinical trial publications were identified that demonstrated benefit in HBO therapy for acute peripheral arterial insufficiency, and thus the evidence basis of the Medicare policy is unclear. Due to the lack of published literature, acute peripheral arterial insufficiency is listed as an additional investigational indication in this policy.

Autism

Hyperbaric oxygen therapy has increased in popularity as a treatment for autism. Rossignol and Rossignol’s (2006) recent research has discovered that some autistic individuals have decreased cerebral perfusion, evidence of neuroinflammation, and increased markers of oxidative stress. In their prospective pilot study of children with autism, HBOT at a maximum pressure of 1.5 ATM with up to 100% oxygen was safe and well tolerated. HBOT did not appreciably worsen oxidative stress and significantly decreased inflammation as measured by C-reactive protein.
(CRP) levels. Parental observations support anecdotal accounts of improvement in several domains of autism. However, since this was an open-label study, definitive statements regarding the efficacy of HBOT for the treatment of individuals with autism must await results from double-blind, controlled trials. No conclusions can be drawn at this time to support HBOT for Autism.

A systematic evidence review of hyperbaric oxygen therapy for autism (Moqadem and Pineau, 2007) was conducted and prepared for a Canadian technology assessment agency, and concluded "that there was insufficient evidence to build a strong case for the efficacy of hyperbaric oxygen therapy in the management of autistic disorders." The authors recommended a literature watch be conducted to evaluate the results of the current and future studies and for now HBO should be considered an “experimental treatment modality.”

Cancer and Tumor Sensitization for Cancer Treatments

In a Randomized Controlled Trial (RCT) of 32 patients, Heys and colleagues (2006) found no increase in 5-year survival in patients treated with HBO prior to chemotherapy for locally advanced breast carcinoma to increase tumor vascularity. This approach has been studied in animal models and suggests that HBO increases tumor vascularity and thus may make chemotherapy more effective. In a Cochrane review, Bennett and colleagues (2005) concluded HBO given with radiotherapy may be useful in tumor control; however, the authors expressed caution since significant adverse effects were common with HBO and indicated further study would be useful.

The American Cancer Society (2007) states that there is no scientific evidence to support HBOT as a cure for cancer or for enhancing tumor response. The National Comprehensive Cancer Network (NCCN, 2008) does not indicate that HBOT is a primary or an adjunctive treatment of cancer. Therefore, HBOT for cancer cures or for tumor sensitization for cancer treatments, including but not limited to radiotherapy or chemotherapy, is considered investigational.

Carbon Tetrachloride Poisoning

High concentrations of carbon tetrachloride produce dizziness, confusion, coma, respiratory depression, hypotension, and sporadic convulsions. Ventricular fibrillation or respiratory failure may lead to death due to cardiac sensitization to circulating catecholamines. Conventional treatment is recommended. There is insufficient evidence to determine health outcomes of HBOT for this indication.

Cerebral Edema

Cerebral edema plays a major role in most traumatic brain injuries, strokes and brain tumors, as well as cerebral infections and abscess, encephalitis and meningitis, and numerous other pathological processes. Hyperbaric oxygen therapy (HBOT) has been proposed as a treatment for minimizing secondary brain damage by improving the oxygen supply to the brain. Bennet et al. (2004) conducted a review of four eligible studies involving 382 patients. The combined results suggested that HBOT reduces the risk of death, however there is no evidence that these survivors have improved outcome in terms of quality of life. The authors concluded that the routine use of HBOT in brain-injured patients cannot be justified by the findings of this review. Due to the small number of trials with a limited number of participants, it is not possible to be confident in
the findings. Further large, high quality trials are required to define the true extent of benefit from HBOT.

**Cerebral Palsy/Brain Injury/Traumatic Brain Injury**

Collet and colleagues (2001) randomized 111 children with cerebral palsy to 40 treatments over a 2-month period of either HBO (n=57) or slightly pressurized room air (n=54). The authors found HBO therapy produced similar improvements in outcomes such as gross motor function and activities of daily living in both groups as slightly pressurized air.

The AHRQ (2003) conducted a systematic evidence review to describe the methods, results, and conclusions of the benefits and harms of hyperbaric oxygen therapy (HBOT) for brain injury, cerebral palsy, and stroke. The authors concluded that the "evidence from well-conducted clinical studies was limited and the balance of benefits and harms of HBOT for brain injury, cerebral palsy, or stroke has not been adequately studied. Future research of HBOT should include dose-ranging and safety studies to establish the optimum course of HBOT to evaluate in outcome studies." In another review by McDonagh et al. (2004) regarding HBOT for traumatic brain injury the authors concluded that the "available evidence for HBOT for traumatic brain injury is insufficient to establish effectiveness or ineffectiveness and call for more high-quality studies on this topic."

**Cerebrovascular Disease (Acute or Chronic)**

Rusyniak and colleagues (2003) reported on the results of a randomized, double-blind sham controlled study of 33 patients presenting with acute ischemic stroke who were randomized to active or sham HBO. No beneficial effect was reported for HBO. In a Cochrane review conducted by Bennet et al. (2005), the authors reviewed the effectiveness and safety of adjunctive HBO in the treatment of acute ischemic stroke. Three randomized controlled trials were included in the review of 106 patients. The authors advised that there is insufficient evidence to make any determinations regarding the safety and efficacy of HBOT for stroke patients at this time.

**Chronic Osteomyelitis**

The treatment of chronic or refractory osteomyelitis remains controversial. The 1999 TEC assessment stated that there was inadequate data to permit conclusions regarding HBOT treatment for chronic osteomyelitis. Since the 1999 TEC Assessment, there have been no new prospective clinical trials on chronic refractory osteomyelitis nor are there any trials on acute osteomyelitis, refractory to standard medical management on an unlimited date search of MEDLINE. In accordance, Hailey (2003) conducted a literature review concerning the use of HBOT for the Alberta Heritage Foundation for Medical Research. Again, no consensus could be reached by the authors regarding the appropriateness of HBOT in relationship to osteomyelitis due to the lack of study evidence. Published textbook direction has also been limited and conflicting. While some reports suggest that use of HBOT as adjunctive therapy may decrease amputations and bed days, there is insufficient evidence to support HBOT for the treatment of chronic osteomyelitis.
Delayed Onset Muscle Soreness and Closed Soft Tissue Injury

Bennett and colleagues (2005) in a Cochrane systematic review of the literature concluded available evidence is insufficient to demonstrate beneficial outcomes with HBO for delayed-onset muscle soreness and closed soft tissue injury. It was noted that HBO possibly even increases pain initially and further studies are needed.

Demyelinating Diseases (i.e., Amyotrophic Lateral Sclerosis (ALS), Multiple Sclerosis (MS))

Steele et al. (2004) treated 5 patients with amyotrophic lateral sclerosis with HBO and reported some improvements in fatigue but noted further study is needed and attention to placebo effects must be given. A number of randomized studies were done based on the suggestion by James (1982) that the use of HBOT for MS would produce vasoconstriction with increased oxygen delivery and some anecdotal evidence of efficacy. The resultant studies showed mixed reports. In 2001, the UHMS and most neurologists abandoned the concept of listing HBOT as a treatment option for MS. An analysis of these studies showed no consistent evidence confirming any beneficial effect of HBOT for the treatment of Multiple Sclerosis (MS) compared to sham treatment. Therefore there is insufficient evidence to support HBOT for MS or Amyotrophic Lateral Sclerosis (ALS).

Fracture Healing and Bone Grafts

The use of HBOT as an adjunct to fracture healing has been proposed to assist in improving healing outcomes in delayed or nonunion fractures. In a Cochrane systematic review, Bennett et al. (2004) concluded that although the use of HBOT for this indication has been proposed for years, there is insufficient evidence within the literature to support or refute its use for the treatment of fractures, aide in the healing of acute injuries, and or assist in the healing process of a non-union fracture.

Hydrogen Sulfide Poisoning

Hydrogen Sulphide (H2S) is a toxic gas produced in decaying substances containing organic sulfur. Exposure to the gas causes severe disturbances in the central nervous and respiratory systems. Treatment of H2S poisoning includes mechanical ventilation with 100% oxygen and immediate administration of sodium nitrate. Treatment with hyperbaric oxygen has been studied in animal models, and has also been used in a number of patients. However, the clinical effectiveness of this mode of therapy has not been clearly proven.

In Vitro Fertilization (IVF)

Van Voorhis and colleagues (2005) reported HBO was well tolerated in women undergoing ovarian follicular stimulation for in vitro fertilization; however no outcomes were reported and further study is needed. Mitrovic et al. (2006) reported a case study of using HBO to improve endometrial preparation prior to IVF. The researchers could not determine if HBO had a direct result on the successful pregnancy.

Lyme disease

The International Lyme and Associated Diseases Society in 2004 developed an evidence based guideline for the management of Lyme disease. The use of hyperbaric oxygen in the treatment of Lyme disease was specifically not recommended for routine therapeutic use. Wormser et al.
Medical Policy: Hyperbaric Oxygen Therapy (HBOT)
Original Policy Date: 5/16/1984
Effective Date: 12/05/2008

(2006) also developed guidelines for Lyme disease and stated that due to the lack of biologic plausibility, lack of efficacy, absence of supporting data, or the potential for harm to the patient, HBOT could not be recommended for the treatment of patients with any manifestation of Lyme disease.

**Malignant Otitis Externa**

Malignant otitis externa is mainly found in the elderly or diabetics. While uncommon, it can be potentially fatal when an infection of the external ear canal includes the surrounding soft tissue and bone. Treatments include antibiotics, stringent diabetes control, the repeated removal of dead tissue and surgical management. Hyperbaric oxygen therapy is increasingly being used in addition to these treatments where facilities exist. A Cochrane review by Phillips et al. (2005) summarized that no clear evidence exists to demonstrate the efficacy of hyperbaric oxygen therapy when compared to treatment with antibiotics and/or surgery. No data were found to compare rates of complication between the different treatment modalities. Further research is required.

**Migraine**

In 2001, Nilsson conducted a double-blind, placebo-controlled crossover study of hyperbaric oxygen treatment on active cluster headaches. The control group consisted of 10 patients with chronic or episodic cluster headache and the experimental group consisted of 12 non-cluster headache sufferers. The control group received sham treatment and 10% oxygen and the experimental group received HBO treatment with 100% oxygen using the same protocols. Researchers measured a number of serum markers of vasoactivation but reported no significant findings, and the results were poorly reported with apparent post hoc comparisons. There is insufficient evidence to support HBOT for cluster headache.

In a randomized, double-blind, placebo-controlled study of 40 patients, Eftedal and colleagues (2004) reported no significant reductions in migraine occurrence with HBO therapy compared to hyperbaric air treatments. Specifically, HBOT did not reduce the amount of attack abortive drugs used and it had no measurable influence on endothelian-1 levels in the blood. HBO as a treatment modality for migraine has not been established at this time.

**Necrotizing Soft Tissue Infections**

The literature review identified a retrospective study and a review on HBO for necrotizing soft tissue infections that provide conflicting conclusions. Wilkinson and Doolette (2004) reported a reduced incidence of amputation in 44 patients with necrotizing soft tissue infections in a retrospective cohort study. However, in a review of MEDLINE and PubMed literature, Jallali et al. (2005) concluded that further study is needed since inconsistent results were found from the studies identified on HBO therapy for necrotizing fasciitis.

**Organ Transplant and Storage**

Experimental studies have suggested that hyperoxemia provided by hyperbaric oxygen may be beneficial in the treatment of reperfusion injury. Hyperbaric oxygen seems to be a promising candidate as a bridge to transplantation, keeping the donated organs viable until the harvesting procedure can take place for potential brain dead donors. However, further investigation on HBO's role in donor organ preservation is needed. Researchers have also hypothesized that the
use of HBO may enhance performance and growth of pancreatic islet grafts. Currently the
efficacy of using HBOT in preparation of and during islet transplantation in animal studies is
being conducted.

**Pyoderma gangrenosum**

Pyoderma gangrenosum (PG) is a rare neutrophilic dermatosis of skin and subcutaneous tissue
and thought to be an immunologic-based phenomenon. Several therapies have been used to
control this disease, including corticosteroids, antibiotics, immunotherapy, dapsone, and
hyperbaric oxygen therapy. Tetrol et al. (2007) derived information from multiple searches of
MEDLINE and the National Baromedical Service literature collection. The authors concluded
"that HBO therapy has been shown to effectively treat PG ulcers and reduce pain associated with
PG in several case studies. Evidence from the studies cited herein help to establish a foundation
for further research to investigate the role of HBO therapy as an adjuvant therapy in the
treatment of PG." At this time there is insufficient evidence to support this indication and further
study is required.

**Refractory Mycoses/Actinomycosis**

Mycosis refers to any condition caused by a fungus and can include systemic infections
involving organs and body systems or superficial infections of the skin. Refractory mycosis is
also known as mucormycosis, actinomycosis, and canidiobolus coronato. Some recent reports
appear positive however there is insufficient evidence to support HBOT use for the treatment of
refractory mycoses.

**Retinal Artery Occlusion and Scleral Thinning**

Beiran et al. (2001) conducted a comparative retrospective study to assess whether early
hyperbaric oxygenation treatment had a beneficial effect on visual results after Retinal Artery
Occlusion (RAO). The authors concluded that early HBOT appears to have a beneficial effect on
visual outcome in patients with RAO. However, further large-scale prospective controlled
studies are needed to confirm this.

A survey of ophthalmologists was conducted by Ogus and Sobaci (2008) regarding the use of
hyperbaric oxygen therapy in ophthalmology. The authors advised that eye diseases are one of
the off-label uses of hyperbaric oxygen. The authors reported "an increasing body of evidence
showing its safety and efficacy for the treatment of retinal artery occlusion, cystoid macular
edema secondary to retinal vein occlusion, scleral thinning and necrosis faced after pterygium
surgery, orbital rhino-cerebral mucymycosis, non-healing corneal edema, and anterior segment
ischemia." While hyperbaric oxygen's potential looks promising in ophthalmology, there is
insufficient evidence to support its use at this time. Further study is needed.

**Senility, Dementia, or Cognitive Impairment**

Raskin et al. (1978) conducted a study of eighty-two elderly subjects with significant cognitive
impairment. The subjects were randomly assigned to treatment with hyperbaric oxygen,
hyperbaric air, normobaric oxygen, or normobaric air. Treatment consisted of two 90-minute
sessions a day for 15 consecutive days. Subjects were evaluated on measures of memory and
intellectual capacity, as well as on psychiatric symptom rating scales. Results immediately after
treatment and at one, two, three, and eight weeks following treatment did not show enhanced
cognitive functioning or significantly greater symptom reduction in experimental subjects who received either normobaric or hyperbaric oxygen as compared to controls who received hyperbaric or normobaric air. In CURRENT 2005, Eisendrath advised that there was insufficient evidence to support the treatment of dementia with HBOT.

**Sickle Cell Disease**

Sickle cell disease is a hereditary disorder of hemoglobin structure and function. The anemia of sickle cell disease is due to both chronic and acute hemolysis making the red cell membranes damaged by repeated episodes of sickling. Several new approaches to treatment of sickle-cell disease are currently under evaluation but these approaches do not include HBOT. There is no evidence that HBOT should be used in the treatment of sickle-cell anemia.

**Spinal Cord Injuries**

There have been no controlled studies regarding the adjunctive use of HBO in the treatment of spinal cord injuries. Only three small, uncontrolled case series with differing ranges of spinal cord injury have been identified. Results were reported as not favorable. Rowland (2005) reported that this indication was never widely accepted. Therefore there is a lack of clinical evidence to support this indication.

**Sudden Sensorineural Hearing Loss and Tinnitus**

Topuz and colleagues (2004) reported on a trial that randomized 51 patients with sudden idiopathic sensorineural hearing loss to receive conventional therapy (i.e., steroids, plasma expanders) with or without HBO. Audiologic assessment was performed immediately after treatment. While the HBO group reported gains in hearing at some frequencies, this small trial with short follow-up is inadequate to permit scientific conclusions. A Cochrane review of 5 trials with a total of 254 patients also concluded that the data are insufficient to determine the clinical significance of hearing improvement with the use of HBO therapy in patients with idiopathic sudden sensorineural hearing loss. It was further stated that there is no evidence of a beneficial effect of HBOT on chronic presentation of idiopathic sudden sensorineural hearing loss and/or tinnitus and HBOT could not be recommended for this purpose based on the single study available.

An additional study by Porubsky et al. (2007) analyzed the effectiveness of HBOT on tinnitus in the context of pretreatment expectations. The authors reported that the success rate of HBO in tinnitus appeared to be influenced by psychological factors and by the anticipation of the patient prior to treatment. HBO therapy was not found to have results beyond placebo effects. Further studies are needed.

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.
Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

*This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement Policy.*

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<th>Type</th>
<th>Number</th>
<th>Description</th>
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<td>Physician attendance and supervision of hyperbaric oxygen therapy, per session</td>
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<tr>
<td>HCPC</td>
<td>A4575</td>
<td>Topical hyperbaric oxygen chamber, disposable</td>
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<td></td>
<td>C1300</td>
<td>Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval</td>
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<td>Place of Service</td>
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**Prior Authorization Requirements**

This service (or procedure) is considered medically necessary in certain instances and investigational in others (refer to policy for details). For instances when the indication is medically necessary, clinical evidence is required to determine medical necessity.

For instances when the indication is investigational, you may submit additional information to the Prior Authorization Department.

Within 5 days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-343-1691 or visit the Provider Portal www.blueshieldca.com/provider
Documentation Required for Clinical Review

- History and physical and/or consultation
- Diagnosis requiring Hyperbaric oxygen therapy
- HBO Treatment Plan including: type of treatment, settings, number and duration of sessions
- Operative report(s) (if applicable)
- Medical treatment for HBOT diagnosis; including adjunctive treatment, medications etc.
- Wound description; including age of wound; Wagner wound classification/staging; treatments over the last 30 days and wound therapy program; and wound progress (if applicable)
- Progress Notes indicating treatment response (if available)

References

- 1999 TEC Assessments. 1999 TEC Assessments; Tab 13
- 1999 TEC Assessments. 1999 TEC Assessments; Tab 15
- 1999 TEC Assessments. 1999 TEC Assessments; Tab 16
• Benan Bayrakci. Preservation of organs from brain dead donors with hyperbaric oxygen. Pediatric Transplantation; Volume 12, Issue 5, Date: August 2008, Pages: 506-509
• Camporesi EM. Hyperbaric oxygen therapy: a committee report. 1996. Undersea and Hyperbaric Medical Society. Kensington, MD
• Feldmeier JJ. Hyperbaric Oxygen 2003: Indications and Results. The Hyperbaric Oxygen Therapy Committee Report. Undersea and Hyperbaric Medical Society. Kensington, Maryland. Guidelines and additional information can be found at www.uhms.org/Indications/indications
• Hampson NB, Corman JM. Rate of delivery of hyperbaric oxygen treatments does not affect response in soft tissue radionecrosis. Undersea Hyperb Med 2007; 34(5):329-34
• I Goldenberg, O Shoshani, Y Mushkat, Y Bentur, Y Melamed, A Shupak. Hyperbaric oxygen for hydrogen sulfide poisoning Harefuah. 1994 Nov 1;127(9):300-2, 360
Medical Policy: Hyperbaric Oxygen Therapy (HBOT)

Original Policy Date: 5/16/1984
Effective Date: 12/05/2008

- Moqadem K, Pineau G. The role of hyperbaric oxygen therapy in the management of autism [summary]. Montreal, QC: Agence d'Evaluation des Technologies et des Modes d'Intervention en Sante (AETMIS); 2007
• Topuz E, Yigit O, Cinar U et al. Should hyperbaric oxygen be added to treatment in idiopathic sudden sensorineural hearing loss? Eur Arch Otorhinolaryngol 2004; 261(7): 393-6
Index/Cross Reference of Related Blues Shield of California (BSC) Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

Key / Related Searchable Words

- HB02
- Hyperbaric oxygen treatment
- Extreme Chamber therapy

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
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<td>New Policy Adoption</td>
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<td>10/11/1995</td>
<td>Policy Revision</td>
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<td>6/07/2000</td>
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<td>Policy Clarification</td>
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The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.