Medical Policy

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Title: Hyperbaric Oxygen-Pressurization (HBO)

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DESCRIPTION

Hyperbaric oxygen therapy (HBO) involves breathing 100% oxygen at a pressure of more than 1 atmosphere (atm). Hyperbaric oxygen therapy is generally applied systemically with the patient inside a hyperbaric chamber. It can also be applied topically; that is, the body part to be treated is isolated e.g., in an inflatable bag and exposed to pure oxygen.

Hyperbaric oxygen therapy (HBO) is a technique of delivering higher pressures of oxygen to the tissues. Two methods of administration are available. 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 oxygen at sea level). Thus, this technique relies on systemic circulation to deliver highly oxygenated blood to the target site, typically a wound. In addition, systemic hyperbaric oxygen therapy can be used to treat systemic illness, such as air or gas embolism, carbon monoxide poisoning, clostridial gas gangrene, etc.

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 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 as a treatment of skin ulcerations resulting from diabetes, venous stasis, postsurgical infection, gangrenous lesion, decubitus ulcers, amputations, skin graft, burns, or frostbite.

Regulatory Status

In February 1999, the Numobag™ Kit (Numotech, Inc; Woodland Hills, CA) for application of topical hyperbaric therapy was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices.

In May 2005, the ATA Monoplace Hyperbaric System (ATA Hyperbaric Chamber Manufacturing, Inc.) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing hyperbaric devices.

POLICY

A. Systemic hyperbaric oxygen pressurization is considered **medically necessary** in the treatment of any of the following conditions when performed in accordance with Undersea and Hyperbaric Medical Society (UHMS) guidelines:
   1. Acute peripheral arterial insufficiency; **or**
   2. Acute thermal burns: deep second degree or third degree in nature; **or**
   3. Acute traumatic ischemia (e.g. crush injuries, reperfusion injury, compartment syndrome); **or**
   4. Carbon monoxide poisoning; **or**
   5. Central retinal artery occlusion; **or**
   6. Cyanide poisoning; **or**
   7. Chronic non-healing wounds which have not responded to 30 treatments of appropriate conservative treatment and which show continued response when evaluated at 30 treatment intervals; **or**
   8. Chronic refractory osteomyelitis (refractory osteomyelitis); **or**
   9. Compartment syndrome; **or**
   10. Compromised skin graft or flaps (enhancement of healing in selected wounds); **or**
   11. Decompression sickness; **or**

12. Delayed radiation injury, including osteoradionecrosis, soft tissue radiation necrosis, and radiation cystitis; **or**
13. Gas or air embolism; **or**
14. Gas gangrene (i.e., clostridial myositis and myonecrosis); **or**
15. Intracranial abscess; **or**
16. Necrotizing soft-tissue infections; **or**
17. Prophylactic pre and post treatment for individuals undergoing dental surgery of a radiated jaw; **or**
18. Severe anemia with exceptional blood loss: when transfusion is impossible or delayed.

B. Topical hyperbaric oxygen therapy is considered **experimental / investigational**.

C. Hyperbaric oxygen pressurization is considered **experimental / investigational** in the treatment of the following conditions, but limited to:
1. acute osteomyelitis, refractory to standard medical management;
2. acute surgical and traumatic wounds;
3. spinal cord injury;
4. traumatic brain injury;
5. severe or refractory Crohn's disease;
6. acute brown recluse spider bites;
7. bone grafts;
8. carbon tetrachloride poisoning, acute;
9. cerebrovascular disease, acute (thrombotic or embolic) or chronic;
10. fracture healing;
11. hydrogen sulfide poisoning;
12. intra-abdominal abscesses;
13. lepromatous leprosy;
14. meningitis;
15. Pseudomembranous colitis (antimicrobial agent-induced colitis);
16. radiation myelitis;
17. sickle cell crisis and/or hematuria;
18. demyelinating diseases, e.g., multiple sclerosis, amyotrophic lateral sclerosis;
19. retinopathy, adjunct to scleral buckling procedures in patients with sickle cell peripheral retinopathy and retinal detachment;
20. pyoderma gangrenosum;
21. acute coronary syndromes and as an adjunct to coronary interventions, including but not limited to, percutaneous coronary interventions and cardiopulmonary bypass;
22. idiopathic sudden sensorineural hearing loss;
23. refractory mycoses: mucormycosis, actinomycosis, canidiobolus coronato;
24. cerebral edema, acute;
25. migraine;
26. in vitro fertilization;

27. cerebral palsy;
28. tumor sensitization for cancer treatments, including but not limited to, radiotherapy or chemotherapy;
29. delayed onset muscle soreness;
30. idiopathic femoral neck necrosis;
31. chronic arm lymphedema following radiotherapy for cancer;
32. radiation-induced injury in the head and neck;
33. early treatment (beginning at completion of radiation therapy) to reduce adverse effects of radiation therapy;
34. autism spectrum disorders;
35. bisphosphonate-related osteonecrosis of the jaw
36. acute ischemic stroke; and
37. Bell's palsy.

Policy Guidelines

Systemic Hyperbaric Oxygen

The Wagner classification system of wounds is defined as follows: grade 0, no open lesion; grade 1, superficial ulcer without penetration to deeper layers; grade 2, ulcer penetrates to tendon, bone, or joint; grade 3, lesion has penetrated deeper than grade 2 and there is abscess, osteomyelitis, pyarthrosis, plantar space abscess, or infection of the tendon and tendon sheaths; grade 4, wet or dry gangrene in the toes or forefoot; grade 5, 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.

Below are suggestions from the Undersea and Hyperbaric Medical Society's (UHMS) 2008 Hyperbaric Oxygen Therapy Committee report on utilization of hyperbaric oxygen therapy (HBO) (1):

1. Enhancement of healing in problem wounds: Treatments are performed for 90 to 120 minutes. The initial treatment schedule depends on the severity of disease. More serious conditions may require twice daily treatments; when stabilized, this can decrease to once daily. Utilization review is required after the initial 30 days of treatments and at least once every additional 30 days.
2. Crush injury, compartment syndrome and other acute traumatic ischemias:
    a. Reperfusion injury: 1 treatment.
    b. Crush injury: 8-12 treatments (three times per day for 2 days, then twice a day for 2 days and daily for 2 days)
    c. Compartment syndrome: 3-4 treatments (twice a day for 1 day and one treatment on day 2)
3. Decompression sickness: The majority of cases respond to a single treatment. Patients with residual defects after the initial session should receive additional treatments until they achieve clinical stability (generally no more than 5-10 treatments). Utilization review is recommended after 10 treatments.
4. Gas embolism, acute: It is recommended that treatments continue until there is no additional improvement; this typically occurs after 1-2 treatments but occasionally up to 5-10. Utilization review is recommended after 10 treatments.

5. Acute carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning: Some patients improve after a single treatment. Patients who fail to demonstrate a full recovery should receive additional treatments. In patients with persistent neurologic dysfunction after the initial treatment, further treatment can occur within 6-8 hours and can be continued once or twice daily until there is no additional improvement in cognitive function. Utilization review is mandatory after the fifth treatment.
6. Soft-tissue radiation necrosis (e.g., radiation enteritis, cystitis, proctitis) and osteoradionecrosis: Most treatment courses for radiation injury will be 30-60 treatments (once daily for 90 to 120 minutes). Utilization review is recommended after 60 treatments.
7. Mandibular osteoradionecrosis: The initial course of treatment for patients with stage 1 osteoradionecrosis is 30 sessions, followed by only minor bony debridement. If response is adequate, an additional 10 treatments are given. If patients are not responding they are considered stage II and they receive more extensive surgical debridement, followed by 10 additional treatments. Patients who present as stage III patients receive 30 treatments followed by mandibular segmental resection and then an additional 10 treatments.
8. Gas gangrene (i.e., clostridial myonecrosis): Recommended are three 90-minute treatments during the first 24 hours and then two treatments per day for the next 2-5 days, depending on the patient's initial response. Utilization review is indicated after 10 treatments.
9. Severe anemia: HBO can be considered for severe anemia when patients cannot receive blood products due to medical, religious, or strong personal preference reasons. Treatment can occur for periods of up to 3 or 4 hours three to four times a day if patients receive intra-treatment air breaks. HBO treatment should be continued with taper of both time and frequency until red blood cells have been satisfactorily replaced by patient regeneration or the patient can undergo transfusion.
10. Chronic refractory osteomyelitis: No recommendations were made for the total number of treatments required. For patients who respond to initial treatment with antibiotics, surgical debridement and HBO, therapy should be continued for approximately 4-6 weeks. Utilization review is indicated after 30-40 sessions.

RATIONALE

Topical Hyperbaric Oxygen

Due to their different methods of delivery, topical and systemic hyperbaric oxygen (HBO) are distinct technologies such that they must be examined separately. At the time of policy development, there was minimal published literature regarding topical hyperbaric oxygen therapy. The literature primarily consists of case reports or small uncontrolled case series. (2, 3) There was one small randomized controlled trial (RCT) that included 18 patients with diabetic foot ulcers who were assigned to receive either topical hyperbaric oxygen therapy plus standard wound care or standard wound care alone. (4) Changes in ulcer size and depth did not differ between the 2 groups.

Systemic Hyperbaric Oxygen

The original policy on systemic HBO was based entirely on the 1996 guidelines published by the Undersea and Hyperbaric Medical Society (UHMS) and was subsequently revised in 1999 with 3 TEC Assessments. (5-7) The TEC Assessments had conclusions similar to UHMS, except, in contrast to the UHMS guidelines, they concluded that there was insufficient evidence to conclude that HBO treatment improved the net health outcome for the following indications:

- compromised skin grafts
- acute thermal burns
- chronic refractory osteomyelitis
- necrotizing soft tissue infections
- brown recluse spider bites

The TEC Assessments also concluded that there was insufficient evidence to permit conclusions on the use of HBO for treatment of brain injury; spinal cord injury; and Crohn's disease, indications not addressed by the 1996 UHMS Guidelines. Literature updates have focused on identifying new RCTs and meta-analyses of RCTs, particularly on indications considered investigational at the time of the update.

Chronic Wounds

An updated Cochrane review of RCTs on HBO treatment for chronic wounds was published by Kranke and colleagues in 2012. (8) The authors identified 9 RCTs with a total of 471 participants that compared the effect of HBO on chronic wound healing compared to an alternative treatment approach that did not use HBO. Eight of the 9 trials included in the review evaluated HBO therapy in patients with diabetes. The remaining trial addressed HBO for patients with venous ulcers; that study had only 16 participants and the comparator treatment was not specified. In a pooled analysis of data from 3 trials, a significantly higher proportion of ulcers had healed at the end of the treatment period (6 weeks) in the group receiving HBO compared to the group not receiving HBO (risk ratio [RR]: 5.20: 95% confidence interval [CI]: 1.25 to 21.7). Pooled analyses, however, did not find significant differences between groups in the proportion of ulcers healed in the HBO versus non-HBO-treated groups at 6 months (2 trials) or 12 months (3 trials). There were insufficient data to conduct pooled analyses of studies evaluating HBO for treating patients with chronic wounds who did not have diabetes. The most recently published trial conducted with diabetic patients was double-blind and included 75 diabetic patients with chronic wounds who had failed at least 2 months of treatment at a diabetic foot clinic. (9) After 12 months, the healing rate was 61% in the hyperbaric oxygen group and 27% in the sham hyperbaric group; this difference was statistically significant, p=0.009.

Based on the above evidence, HBO therapy for chronic severe diabetic ulcers may be considered medically necessary, and HBO treatment for other types of chronic wounds is considered investigational.

Acute Surgical and Traumatic Wounds

In 2011, a Cochrane review of RCTs on HBO therapy for acute wounds (e.g., surgical wounds, lacerations, traumatic wounds, and animal bites) was published by Eskes and colleagues. (10)

To be included, studies needed to compare HBO with a different intervention or compare 2 HBO regimens; in addition, studies needed to objectively measure wound healing. A total of 7 potentially relevant studies were identified; 3 of these met the review's inclusion criteria. The 3 studies ranged in size from 36 to 135 participants. Due to differences among studies in terms of patient population, comparison intervention, outcome measurement, etc., study results could not be pooled. In addition, investigators identified biases in the studies such as insufficient reporting of randomization procedures and selective reporting of outcome data. Findings of individual studies were mixed. For example, one study found a significantly higher rate of complete wound healing with HBO compared to sham HBO treatment, and another study did not find a significant difference in complete healing rates between HBO therapy and dexamethasone or heparin treatment. The authors concluded that there is insufficient high-quality data on the effect of HBO therapy on treatment of acute wounds.

Carbon Monoxide Poisoning

A 2011 Cochrane review of 7 RCTs concluded that the available evidence is insufficient to determine whether adverse neurologic outcomes in patients with carbon monoxide poisoning are reduced with HBO therapy. (11) In 2008, the American College of Emergency Physicians published a clinical policy on critical issues in carbon monoxide poisoning. (12) Their literature review indicated there was only Level C evidence (preliminary, inconclusive, or conflicting evidence) for treatment of acute carbon monoxide poisoning. The 2008 Undersea and Hyperbaric Medical Society (UHMS), however, lists carbon monoxide poisoning as an indication for HBO therapy.

Two blinded randomized trials were discussed in both the Cochrane and American College of Emergency Physicians reviews. One is a study by Scheinkestel and colleagues, a double-blind, RCT comparing HBO to normobaric oxygen in patients with carbon monoxide poisoning. (13) The authors reported that HBO therapy did not benefit patient outcomes of neuropsychologic performance when HBO therapy was completed and at 1-month follow-up. This study was limited, however, by a high rate (46%) of patients who were lost to follow-up. Moreover, the trial has been criticized for administrating 100% normobaric oxygen for at least 72 hours between treatments, which has been called a toxic dose of oxygen. (14) The critiques also mention that there was an unusually high rate of neurologic sequelae after the treatment period, which could be due in part to the high dose of oxygen and/or the high rate of cognitive dysfunction in the study population (69% were poisoned by carbon monoxide through suicide attempts).

The other blinded trial by Weaver and colleagues also compared HBO and normobaric oxygen. (15) Patients received either 3 sessions of HBO or 1 session of normobaric oxygen plus 2 sessions of exposure to normobaric room air. The primary outcome was the rate of cognitive sequelae at 6 weeks. Cognitive function was assessed by a battery of neuropsychological tests. At the 6-week follow-up, the intention-to-treat analysis found that 19 of 76 (25.0%) in the HBO group and 35 of 76 (46.1%) in the control group had cognitive sequelae; the difference was statistically significant, p=0.007. There was a high rate of follow-up at 6 weeks, 147 of 152 (97%) of randomized patients. Enrollment in the study was stopped early because an interim analysis found HBO to be effective. A follow-up study, that included 147 patients from the randomized trial and 75 who had been eligible for the trial but had not enrolled, was published in 2007. (16) Of the group treated with HBO (n=75), cognitive sequelae were identified in 10 of

58 (17%) at 6 months and 9 of 62 (14%) at 12 months. Of the group not treated with HBO (n=163), 44 of 146 (30%) at 6 months and 27 of 149 (18%) at 12 months had cognitive sequelae. (The follow-up rate was higher at 12 months because the investigators received additional funding for data collection). Thus, in light of the clinical studies, including the limitations of trials noted above, and given the strong clinical support for this treatment (see Clinical Input section below), the use of hyperbaric oxygen therapy for acute carbon monoxide poisoning may be medically necessary.

Radionecrosis and Osteoradionecrosis

A 2008 Cochrane review by Esposito et al. reviewed the use of HBO therapy in patients requiring dental implants. (17) 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 need for more RCTs to ascertain the effectiveness of HBO in irradiated patients requiring dental implants.

In 2012, Bennett and colleagues published a Cochrane review on hyperbaric oxygen therapy for late radiation tissue injury. (18) The authors identified 11 RCTs; there was variability among trials and study findings were not pooled for the primary outcomes of survival, complete resolution of necrosis or tissue damage, and improvement in a late effects symptom scale. In a pooled analysis of 3 studies, a significantly higher proportion of patients with osteoradionecrosis achieved complete mucosal cover after hyperbaric oxygen treatment compared to control (RR: 1.30, 95% CI: 1.09 to 1.55). From their review of the literature, the authors concluded that data from small trials "suggest that for people with LRTI (Late Radiation Tissue Injury) affecting the head, neck, anus, and rectum, [HBO] is associated with improved outcome. HBO also appears to reduce the chance of ORN (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."

In 2012, Shao and colleagues in China published an RCT including 36 patients who had undergone radiotherapy for pelvic malignancies and had radiation-induced hemorrhagic cystitis. (19) Patients were randomized to treatment with hyaluronic acid (n=16) or hyperbaric oxygen (n=20). The hyaluronic acid group received weekly injections for the first month and monthly injections for the following 2 months. HBO treatment consisted of 30-minute sessions daily for one month. All patients completed the study. There were no statistically significant differences in outcomes e.g., pain or voids per day 6, 12, or 18 months after treatment. For example, at 12 months after treatment, the number of voids per day was 8.9 in the hyaluronic acid group and 9.7 in the HBO group, $p>0.05$. The study may have been underpowered to detect statistically significant differences between groups.

In summary, given the longstanding use of this technology, the existing literature base, and the Cochrane reviews noted above, the use of HBO therapy 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 may be considered medically necessary.

Bisphosphonate-related Osteonecrosis of the Jaw

An unblinded RCT was published by Freiberger and colleagues in 2012 on use of HBO as an adjunct therapy for patients with bisphosphonate-related osteonecrosis of the jaw. (20) Forty-nine patients were randomly assigned to HBO in addition to standard care (n=22) or standard care alone (n=27). Five patients in the standard care group received HBO treatment and 1 patient assigned to the HBO group declined HBO. The investigators decided to do a per protocol analysis (actual treatment received) because of the relatively large degree of crossover. Participants were evaluated at 3, 6 12 and 18 months. Data were available on 46 patients, 25 received HBO in addition to standard care and 21 received standard care alone. The primary outcome measure was change in oral lesion size or number. When change from baseline to last available follow-up was examined, 17 of 25 (68%) of HBO-treated patients had improvement in oral lesion size or number compared to 8 of 21 (38%) in the standard care group, p=0.043. When change from baseline to 6, 12 or 18 months was examined, there was not a statistically significant difference between groups in the proportion of patients with improvement. In addition, the proportion of patients who healed completely did not differ significantly between groups at any time point. This single trial does not report consistent findings of benefit across outcome measures. It also has a number of methodologic limitations, e.g., unblinded, cross-over, and analysis performed on a per-protocol basis rather than intention to treat. A disadvantage of the per-protocol analysis is that randomization is not preserved, and the two groups may differ on characteristics that affect outcomes. As a result, this trial is insufficient to conclude that HBO improves health outcomes for patients with bisphosphonate-related osteonecrosis of the jaw.

Osteomyelitis

No prospective clinical trials on chronic refractory osteomyelitis or acute refractory osteomyelitis were identified in updated searches. The justification for the use of HBO in chronic osteomyelitis has been primarily based on case series. Among the larger case series, Maynor and colleagues reviewed the records of all patients with chronic osteomyelitis of the tibia seen at one institution. (21) Follow-up data were available on 34 patients who had received a mean of 35 adjunctive HBO treatments (range, 6 to 99). Of the 26 patients with at least 2 years of follow-up after treatment, 21 (81%) remained drainage-free. Twelve of 15 (80%) with follow-up data at 60 months had remained drainage-free. A study by Davis and colleagues reviewed outcomes for 38 patients with chronic refractory osteomyelitis treated at another U.S. institution. (22) Patients received HBO treatment until the bone was fully recovered with healthy vascular tissue; this resulted in a mean of 48 daily HBO treatments (range, 8 to 103). After a mean post-treatment follow-up of 34 months, 34 of 38 (89%) patients remained clinically free of infection (i.e., drainage-free and no tenderness, pain, or cellulitis). Success rates from several smaller case series, all conducted in Taiwan, are 12 of 13 (92%) patients, 11 of 14 (79%) patients, and 13 of 15 (86%) patients. (23-25) Given the high percentage of refractory patients in these series who had successful outcomes and the clinical support for HBO as a treatment option for chronic refractory osteomyelitis (see Clinical Input section below), the use of HBO therapy for chronic refractory osteomyelitis may be considered medically necessary. HBO treatment for acute osteomyelitis refractory to medical treatment may be considered investigational.

Fracture Healing

In 2012, Bennett and colleagues published a Cochrane review on HBO to promote fracture healing and treat non-union fractures. (26) The investigators did not identify any published RCTs on this topic that compared HBO to no treatment, sham or another intervention and reported bony union as an outcome. Due to the lack of RCTs, it is not possible to conclude whether the use HBO to promote fracture healing improves outcomes; therefore, the use of HBO for this indication is considered investigational.

Compromised Skin Grafts and Flaps

In 2006, Friedman and colleagues published a systematic review of literature on use of HBO for treating skin flaps and grafts. (27) No RCTs were found. The authors identified 2 retrospective case series on use of HBO for clinically compromised skin grafts and flaps. The series had sample sizes of 65 and 26, respectively; both were published in the 1980s based on treatment provided in the 1970s and 1980s. Given the limited published data and lack of recent data, this indication remains investigational.

Necrotizing Soft Tissue Infections

A 2005 systematic review by Jallali and colleagues evaluated the literature on HBO as adjunctive therapy for necrotizing fasciitis. (28) They did not identify any RCTs. There were only a few retrospective studies with small sample sizes and findings were inconsistent. The authors concluded that more robust evidence is needed before widespread use of HBO is recommended. A 2009 retrospective cohort study compared outcomes in 48 patients at 1 center who received adjunctive HBO for necrotizing soft issue infections to those in 30 patients at a different center who did not receive HBO. (29) There was not a significant difference in the mortality rate between the 2 groups; this was 4 of 48 (8%) in the HBO group and 4 of 30 (13%) in the non-HBO group ($p=0.48$). The median number of days in the intensive care unit and the median number of days in the hospital also did not differ significantly. There was a higher median number of debridement procedures per person in the HBO group, 3.0 compared to 2.0 in the non-HBO group ($p=0.03$). Thus, based on the available evidence, HBO for necrotizing soft tissue infections remains investigational.

Refractory Mycoses

No clinical trials on refractory mycoses (mucormycosis, actinomycosis, conidiobolus coronato) and cerebral edema were found. Therefore, these indications were changed to investigational.

Acute Peripheral Arterial Insufficiency

While Medicare has long listed acute peripheral arterial insufficiency as a medically necessary indication, this application was not addressed by previous versions of this policy. 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. (30) Due to the lack of published literature, acute peripheral arterial insufficiency was added as an investigational indication in this policy.

Acute Coronary Syndromes

A 2012 Cochrane review by Bennett and colleagues identified 6 trials with a total of 665 patients evaluating HBO for acute coronary syndrome. (31) All of the studies included patients with acute myocardial infarction (MI); one study also included individuals presenting with unstable angina. Additionally, all trials used HBO as an adjunct to standard care. Control interventions varied; only 1 trial described using a sham therapy to blind participants to treatment group allocation. In a pooled analysis of data from 5 trials, there was a significantly lower rate of death in patients who received HBO compared to a control intervention (RR: 0.58: 0.36 to 0.92). Due to variability of outcome reporting in the studies, few other pooled analyses could be conducted. A pooled analysis of data from 3 trials on improvements in left ventricular function did not find a statistically significant benefit of HBO treatment (RR: 0.09; 95% CI: 0.01 to 1.4). The authors noted that, although there is some evidence from small trials that HBO treatment is associated with a lower risk of death, larger trials with high methodologic quality are needed in order to determine which patients, if any, can be expected to derive benefit from HBO.

One of the trials was by Sharifi and colleagues and randomly assigned 69 patients with unstable angina or MI to receive or not receive HBO after a percutaneous coronary intervention (PCI). (32) The 24 patients randomly assigned to the HBO group reported only 1 adverse event (death, MI, coronary artery bypass, or revascularization of target lesion), compared to 13 in the 37 control patients. However, this study lacked adequate detail, e.g., on the type of PCI performed, to permit scientific conclusions. In another RCT of 64 patients, Alex and colleagues concluded both neuropsychometric dysfunction and inflammatory response can be reduced postcardiopulmonary bypass when HBO pretreatment is given. (33) Based on the above evidence, the treatment of acute coronary syndromes with HBO is considered investigational.

Acute Ischemic Stroke

In a 2005 Cochrane systematic review, Bennett and colleagues evaluated HBO treatment for acute stroke; the content of this review was updated in 2009. (34) The investigators identified 6 RCTs with a total of 283 participants that compared HBO to sham HBO or no treatment. The authors were only able to pool study findings for 1 outcome; the mortality rate at 3-6 months. A pooled analysis of date from 3 trials did not find a significant benefit of HBO compared to a control condition for this outcome (RR: 0.61, 95% CI: 0.17 to 2.20). One of the RCTs was published in 2003 by Rusyniak and colleagues. (35) This double-blind trial included 33 patients presenting with acute ischemic stroke who were randomly assigned to active or sham HBO. No beneficial effect was reported for HBO therapy compared to sham. Based on the available evidence, acute ischemic stroke is considered investigational.

Motor Dysfunction Associated with Stroke

In 2013, Efrati and colleagues published an RCT evaluating HBO therapy for treatment of neurologic deficiencies associated with a history of stroke. (36) The study included 74 patients with at least 1 motor dysfunction who had an ischemic or hemorrhagic stroke 6-36 months prior to study participation. Participants were randomly assigned to receive 2 months of HBO treatment (40 daily sessions, 5 days per week, n=30) or delayed treatment (n=32). Patients were evaluated at baseline and 2 months. For patients in the delayed treatment control group, outcomes were evaluated at 4 months after crossing over and receiving HBO treatment.

Twenty-nine of 32 patients (91%) in the delayed treatment group crossed over to the active intervention. Outcome measures included the National Institutes of Health Stroke Scale (NIHSS), which was measured by physicians blinded to treatment group, and several patient-reported quality-of-life and functional status measures.

At 2 months' follow-up, there was statistically significantly greater improvement in function in the HBO group compared to the control group as measured by the NIHSS, quality-of-life scales and the ability to perform activities of daily living (ADLs). These differences in outcome measures were accompanied by improvements in single-photon emission computed tomography (SPECT) imaging in the regions affected by stroke. For the delayed treatment control group, there was a statistically significant improvement in function after HBO treatment compared to before treatment. This RCT raises the possibility that HBO may induce improvements in function and quality of life for post-stroke patients with motor deficits. However, the results are not definitive for a number of reasons. This RCT is small and enrolled a heterogeneous group of post-stroke patients. The study was not double-blind and the majority of outcome measures, except for the NIHSS, were patient reported and thus prone to the placebo effect. Also, there was a high total dropout rate of 20% at the 2-month follow-up point. Therefore, larger, double-blind studies with longer follow-up are needed to corroborate these results. Because of these limitations in the evidence, HBO is considered investigational for treating motor dysfunction associated with stroke.

Bell's Palsy

In 2012, Holland and colleagues published a Cochrane systematic review evaluating HBO treatment in adults with Bell's palsy. (37) The authors identified one RCT with 79 participants, and this study did not meet the Cochrane review methodologic standards because the outcome assessor was not blinded to treatment allocation. Due to the publication of the Cochrane review and the finding of insufficient evidence, Bell's palsy was added to the investigational statement.

Traumatic Brain Injury

A 2012 Cochrane systematic review addressed HBO as adjunctive treatment for traumatic brain injury. (38) The investigators identified 7 RCTs with a total of 571 participants comparing a standard intensive treatment regimen to the same treatment regimen with the addition of HBO. The review did not include studies in which interventions occurred in a specialized acute care setting. The HBO regimens varied among studies; for example, the total number of individual sessions varied from 3 to 30-40. No trial used sham treatment or blinded the staff members who were treating the patients, and only 1 had blinding of outcome assessment. Allocation concealment was inadequate in all of the studies. The primary outcomes of the review were mortality and functional outcomes. A pooled analysis of data from 4 trials that reported this outcome found a statistically significantly greater reduction in mortality when HBO was added to a standard treatment regimen (RR: 0.69, 95% CI: 0.54 to 0.88). However, when data from the 4 trials were pooled, the difference in the proportion of patients with an unfavorable functional outcome at final follow-up did not quite reach statistical significance (RR: 0.71, 95% CI: 0.50 to 1.01). Unfavorable outcome was commonly defined as a Glasgow Outcome Score (GOS) of 1, 2 or 3, which are described as 'dead', 'vegetative state' or 'severely disabled'. Studies were generally small and were judged to have substantial risk of bias.

A sham-controlled double-blind trial evaluating HBO was published by Wolf and colleagues in 2012. (39) The study included 50 military service members, 48 of whom were male, with combat-related mild traumatic brain injury. Participants were randomized to 30 sessions of HBO over 8 weeks (n=25) or a sham intervention (room air at 1.3 ATA) (n=25). The primary outcome measures were scores on the Immediate Post-Concussive Assessment and Cognitive Testing (ImPACT) and Post-Traumatic Disorder Check List- Military Version (PCL-M) instruments. Patients were evaluated after every 5 treatment sessions and at 6 weeks post-exposure. Forty-eight of 50 participants (96%) completed the study. There were no statistically significant differences on the ImPACT total mean score or the PCL-M composite score at any time point. For example, at the 6 week follow-up, mean composite PCL-M scores were 41.6 in the HBO group and 40.6 in the sham-control group, p=0.28. While the sample size was relatively small, the study was powered to detect clinically significant differences among groups on the cognitive tests.

In summary, systematic review of small trials with limitations found a mortality reduction with HBO but no significant improvement in patient function among survivors of traumatic brain injury. One additional trial, which was double-blind and sham-controlled, did not find a statistically significant benefit of HBO treatment in patients with mild traumatic brain injury. Thus, the evidence is insufficient that HBO treatment improves health outcomes in patients with traumatic brain injury, and this indication is considered investigational.

Idiopathic Sudden Sensorineural Hearing Loss (ISSNHL)

In 2011, the Undersea and Hyperbaric Medical Society added idiopathic sudden sensorineural hearing loss (ISSNHL) within the past 14 days as an approved indication for HBO therapy. (40)

A 2012 Cochrane review on HBO for ISSNHL and tinnitus identified 7 trials with a total of 392 participants. (41) [This is an update of a 2007 review; no additional trials were identified (42)]. All trials included patients with ISSNHL with and/or without tinnitus; 2 trials also included patients with tinnitus in the absence of ISSNHL. Randomization procedures were only described in one study, and only one study stated they blinded participants to treatment group assignment using sham therapy. Six of the studies included time-based entry criteria for hearing loss and/or tinnitus; this was 48 hours in 3 studies, 2 weeks in 2 studies (for acute presentation) and 6 months in 1 study. The dose of oxygen per treatment session and the treatment protocols varied among studies e.g., the total number of treatment sessions varied from 10 to 25. All trials reported on change in hearing following treatment; but specific outcomes varied. Two trials reported the proportion of participants with greater than 50% return of hearing at the end of therapy. A pooled analysis of these studies did not find a statistically significant difference in outcomes between the HBO and control groups (RR: 1.53, 95% CI: 0.86 to 2.78). In contrast, a pooled analysis of 2 trials reporting the proportion of participants with greater than 25% return of hearing at the end of therapy found a significantly higher rate of improvement after HBO compared to a control intervention (RR: 1.39: 95% CI: 1.05 to 1.84). Moreover, a pooled analysis of 4 trials found a significantly greater mean improvement in hearing over all frequencies with HBO compared to control (mean difference: 15.6 decibels (dB); 95% CI: 1.5 to 29.8). The authors stated that, due to methodologic shortcomings of the trials and the modest number of patients, results of the meta-analysis should be interpreted cautiously; they did not recommend use of HBO for treating ISSNHL.

Among the RCTs was a 2004 study by Topuz and colleagues in which 51 patients with ISSNHL were randomized to receive conventional therapy (i.e., steroids, plasma expanders) with or without HBO. (43) Patients were within the first 2 weeks of onset of sudden hearing loss. Audiologic assessment was performed immediately after treatment. Compared to the conventional therapy group, the HBO group reported statistically significant improvement in hearing at frequencies of 250, 500, 1,000, and 4,000 Hz, but not at 2,000 Hz.

In 2012, Suzuki and colleagues in Japan published findings of a non-randomized controlled trial in 276 consecutive patients with ISSNHL. (44) All patients had been treated with intravenous hydrocortisone. In addition, 174 patients underwent HBO treatment and 102 patients received intratympanic dexamethasone injection. There was no significant difference in most outcomes e.g., cure rate, marked recovery rate and hearing gain (dB) between the groups of patients who received HBO treatment compared to dexamethasone injections. However, at the $p<0.05$ level, the recovery rate (complete, good, or fair recovery) was significantly higher in the dexamethasone injection group than the HBO group (79.4% vs. 68%, respectively $p=0.048$). Limitations of this study were that individuals were not randomized to treatment group, and the authors did not adjust the p value to account for multiple outcome variables.

Due to methodologic limitations and variability among published studies, the evidence is insufficient to draw conclusions about the effect of HBO on health outcomes in patients with ISSNHL. Thus, HBO is considered investigational for treating ISSNHL.

Cancer Treatment

In an RCT of 32 patients, Heys and colleagues found no increase in 5-year survival in patients treated with HBO prior to chemotherapy for locally advanced breast carcinoma to increase tumor vascularity. (45) This approach is being studied since studies in animal models have suggested that HBO increases tumor vascularity and thus may make chemotherapy more effective. In a Cochrane review, Bennett and colleagues concluded that 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. (46) Therefore, a policy statement was added to indicate HBO for tumor sensitization for cancer treatments, including but not limited to radiotherapy or chemotherapy, is considered investigational.

In Vitro Fertilization

Van Voorhis and colleagues reported that HBO was well-tolerated in women undergoing ovarian follicular stimulation for in vitro fertilization; however, no outcomes were reported, and further study is needed. (47) In vitro fertilization was added to the list of investigational indications for HBO.

Delayed-onset Muscle Soreness

In a Cochrane review, Bennett and colleagues concluded that available evidence is insufficient to demonstrate beneficial outcomes with HBO for delayed-onset muscle soreness and closed soft tissue injury. (48) It was noted that HBO possibly even increases pain initially and further studies are needed. Therefore, a policy statement was added to indicate HBO for delayed-onset muscle soreness is considered investigational.

Autism Spectrum Disorders

A 2012 systematic review of evidence on hyperbaric oxygen therapy for treatment of children with autism identified 2 RCTs with a total of 89 participants. (49) One of the 2 RCTs found better outcomes after hyperbaric oxygen compared to placebo treatment, and the other did not find significant differences in outcomes. The author concluded that additional sham-controlled trials with rigorous methodology are needed in order to draw conclusions about the efficacy of HBO for treating autism. A 2012 review article also concluded that, although studies to date suggest that HBO is safe and potentially effective, additional studies are warranted. (50) In particular, it was recommended that future studies use standardized behavioral measurement tools and also assess physiological biomarkers.

One of the RCTs was by Rossignol and colleagues. (51) This double-blind trial included 62 children, ages 2-7 years, who met Diagnostic and Statistical Manual of mental Disorders (DSM)-IV criteria for autistic disorder. The active treatment was hyperbaric treatment at 1.3 atmospheres (atm) and 24% oxygen in a hyperbaric chamber. (This regimen differs from standard HBO treatment, which uses 100% oxygen and a pressure of at least 1.4 atm.) The other group received a sham treatment consisting of 1.03 atm and ambient air (21% oxygen). Both groups received 40 sessions of active or sham treatment lasting 60 minutes each over a period of 4 weeks. The equipment, procedures, etc. in the 2 groups were as similar as possible to maintain blinding. The investigators, participants, parents, and clinic staff were blinded to treatment group. Only the hyperbaric technician, who had no role in outcome assessment, was aware of group assignment. After completion of the 4-week study, families with children in the control group were offered the active intervention. When asked at the end of the study, there was no significant difference in the ability of parents to correctly guess the group assignment of their child.

The outcomes were change compared to baseline after 4 weeks on the following scales: Aberrant Behavior Checklist (ABC) total score and 5 subscales: Autism Treatment Evaluation Checklist (ATEC) total score and 4 subscales; and Clinical Global Impression-Improvement (CGI) overall functioning score and 18 subscales. P values of <0.05 were considered statistically significant; there was no adjustment for multiple comparisons. The analysis included all children who completed at least one complete session. Of the 33 children assigned to active treatment, 30 were included in the analysis, and 29 completed all 40 treatments. Of the 29 children assigned to the control treatment, 26 completed all 40 sessions and were included in the analysis.

There was no significant between-group improvement on the ABC total score, any of the ABC subscales, or on the ATEC total score. Compared to the control group, the treatment group had a significant improvement in 1 of 4 subscales of the ATEC, the sensory/cognitive awareness subscale. The change from baseline on this subscale was a mean of 16.5 in the treatment group and a mean of 5.4 in the control group, a difference of 11.1 ($p=0.037$). (Note: due to an administrative error, baseline ATEC was not collected at one site, and thus data were not available for 23 children in the treatment group and 21 children in the control group). On the physician-rated CGI total score, 9/30 (30%) children in the treatment group had a score of 1 (very much improved) or 2 (much improved) compared to 2/26 (8%) in the control group ($p=0.047$). On the parental-rated CGI total score, 9/30 (30%) children in the treatment group had a score of 1 or 2 compared to 4/26 (15%) in the control group ($p=0.22$, not statistically

significant). (The exact numbers receiving scores of 1 vs. 2 were not reported.) Change in mean CGI scores were also reported, but this may be a less appropriate way to analyze these data. Among the parental-rated CGI subscales, significantly more children were rated as improved in the treatment group compared to control on 2 out of 18 subscales, receptive language (p=0.017) and eye contact (p=0.032).

A key limitation of this study was that the authors reported only outcomes at 4 weeks, directly after completion of the intervention. It is not known whether there are any long-term effects. Additional follow-up data cannot be obtained because members of the control group crossed over to the intervention after 4 weeks. Other limitations include lack of adjustment for multiple comparisons and unclear clinical significance of the statistically significant outcomes. The Undersea and Hyperbaric Medical Society (UHMS) issued a position paper after publication of the Rossignol et al. study stating that they still did not recommend routine treatment of autism with HBO. (52)

An additional 2012 RCT, published after the 2012 systematic review had been completed, was conducted in Thailand and randomly assigned 60 children with autism to receive 20 one-hour sessions with HBO or sham air treatment (n=30 per group). (53) The primary outcome measures were change in the ATEC and CGI, evaluated separately by clinicians and parents. There were no statistically significant differences between groups on any of the primary outcomes. For example, post-treatment clinician-assessed mean scores on the ATEC were 52.4 in the HBO group and 52.9 in the sham air group. In summary, there is insufficient evidence from rigorous RCTs that HBO improves health outcomes for patients with autism spectrum disorder; therefore, HBO treatment for this indication is considered investigational.

Amyotrophic Lateral Sclerosis

In the updated searches, no randomized trials were found evaluating HBO for treatment of amyotrophic lateral sclerosis. In a small case series, Steele et al. treated 5 patients with HBO and reported some improvements in fatigue but noted that further study is needed, and attention to placebo effects must be given. (54) Thus, amyotrophic lateral sclerosis was added to the policy as an investigational indication.

Cerebral Palsy

Two published RCTs were identified. In 2012, Lacey and colleagues published a double-blind RCT that included 49 children age 3-8 years with spastic cerebral palsy. (55) Participants were randomized to receive 40 treatments with either HBO (n=25) or hyperbaric air to simulate 21% oxygen at room air (n=24). The primary efficacy outcome was change in the Gross Motor Function Measure (GMFM-88) global score after the 8-week treatment period. The study was stopped early due to futility, when an interim analysis indicated that there was less than a 2% likelihood that a statistically significant difference between groups would be found. At the time of the interim analysis, the post-treatment GMFM-88 global score was a mean of 40.8 (standard deviation [SD]: 33.4) in the HBO group and 41.2 (SD: 29.6) in the hyperbaric air group. The between-group difference was 0.9 (95% CI: -1.5 to 3.3), p value=0.54.

Previously, in 2001, Collet et al. randomly assigned 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).

(56) The authors found HBO produced similar improvements in outcomes such as gross motor function and activities of daily living in both groups as slightly pressurized air. The available evidence does not support HBO as a treatment of cerebral palsy; therefore, this is considered investigational.

Vascular Dementia

A 2012 Cochrane review identified 1 RCT evaluating HBO for the treatment of vascular dementia. (57) The 2009 study, conducted in China compared HBO plus donepezil to donepezil-only in 64 patients. The HBO and donepezil group had significantly better cognitive function after 12 weeks of treatment, as assessed by the Mini-Mental State Examination. The Cochrane investigators judged the trial to be of poor methodologic quality because it was not blinded and the methods of randomization and allocation concealment were not discussed. This single trial with limitations provides insufficient evidence on the efficacy of HBO treatment on vascular dementia; thus, HBO is considered investigational for this indication.

Radiotherapy Adverse Effects

In 2010, Spiegelberg and colleagues conducted a systematic review of studies on HBO therapy to prevent or treat radiotherapy-induced head and neck injuries associated with treatment of malignant tumors. (58) The authors identified 20 studies. Eight of the studies included control groups; their sample sizes ranged from 19 to 78 individuals. Four (50%) of the studies with a control group concluded that HBO was effective, and the other 4 did not conclude that the HBO was effective. The authors noted a paucity of RCTs but did not state the number of RCTs that they identified in their review.

A study by Teguh and colleagues published in 2009 included 17 patients with oropharyngeal or nasopharyngeal cancer who were treated with radiation therapy; the study was conducted in The Netherlands. (59) HBO therapy was used to prevent adverse events following radiotherapy. Eight patients were randomly assigned to receive 30 sessions of HBO, beginning within 2 days of completing radiation therapy, and 9 patients received no additional treatment. All patients were included in the analysis. Quality-of-life outcomes were assessed, and the primary outcome was specified as xerostomia at 1 year. Quality-of-life measures did not differ significantly between groups in the acute phase (first 3 months). For example, 1 month after treatment, the mean visual analog scale (VAS) score for xerostomia (0-to-10 scale) was 5 in the HBO group and 6 in the control group. However, at 1 year, there was a statistically significant difference between groups; the mean VAS score for xerostomia was 4 in the HBO group and 7 in the control group (p=0.002). Also at 1 year, the mean quality-of-life score for swallowing (0-to-100 scale) was 7 in the HBO group and 40 in the control group (p=0.0001). The study is limited by the small sample size and the wide fluctuation over the follow-up period in quality-of-life ratings.

In 2010, Gothard and colleagues in the U.K. published findings of a RCT using HBO therapy to treat arm lymphedema occurring after radiotherapy for cancer. (60) Fifty-eight patients with arm lymphedema (at least 15% increase in arm volume) following cancer treatment were randomized in a 2:1 ratio to receive HBO (n=38) or usual care without HBO (n=20). Fifty-three patients had baseline assessments and 46/58 (79%) had 12-month assessments. At the 12-month follow-up, there was not a statistically significant difference in the change from baseline

in arm volume. The median change from baseline was -2.9% in the treatment group and -0.3% in the control group. The study protocol defined response as at least an 8% reduction in arm volume relative to the contralateral arm. According to this definition, 9 of 30 (30%) of patients in the HBO group were considered responders compared with 3 of 16 (19%) in the control group; the difference between groups was not statistically significant. Other outcomes, e.g., quality-of-life scores on the Short-Form (SF)-36, were similar between groups.

Due to the limited data, use of HBO to treat arm lymphedema or radiation-induced injury in the head and neck after radiotherapy, as well as early use of HBO after radiation therapy to reduce side effects are considered investigational.

Idiopathic Femoral Neck Necrosis

A double-blind RCT that evaluated HBO therapy to treat femoral head necrosis was published in 2010 by Camporesi and colleagues. (61) The study included 20 adult patients with idiopathic unilateral femoral head necrosis. Patients received 30 treatments over 6 weeks with either HBO at 2.5 ATA (n=10) or a sham treatment consisting of hyperbaric air (n=10). The mean severity of pain on a 0-to-10 scale was significantly lower in the HBO group than the control group after 30 sessions ($p<0.001$) but not after 10 or 20 sessions. (The article did not report exact pain scores.) Several range-of-motion outcomes were also reported; degrees were the unit of measurement. At the end of the initial treatment period, extension, abduction and adduction, but not flexion, were significantly greater in the HBO group compared to the control group. Longer-term comparative data were not available because the control group was offered HBO at the end of the initial 6-week treatment period. This single, small short-term RCT represents insufficient data on which to draw conclusions about the efficacy of HBO for treating femoral head necrosis.

Migraine

A Cochrane review by Bennett and colleagues identified RCTs that evaluated the effectiveness of systemic HBO therapy for preventing or treating migraine headache compared to another treatment or a sham control. (62) In a search of the literature through May 2008, 5 trials with a total of 103 patients were identified that addressed treatment of acute migraine with HBO. A pooled analysis of 3 trials (total of 43 patients) found a statistically significant increase in the proportion of patients with substantial relief of migraine within 45 minutes of HBO treatment (RR: 5.97, 95% CI: 1.46-24.38, $p=0.001$). No other pooled analyses were conducted due to variability in the outcomes reported in the trials. The meta-analysis did not report data on treatment effectiveness beyond the immediate post-treatment period, and the methodologic quality of individual trials was moderate to low, e.g., randomization was not well-described in any trial. Based on the above limitations of the meta-analysis and RCTs included in the meta-analysis, use of HBO to treat migraine remains investigational.

Herpes Zoster

In 2012, Peng and colleagues in China published an RCT evaluating HBO as a treatment of herpes zoster. (63) Sixty-eight patients with herpes zoster diagnosed within the previous 2 weeks were randomized to 30 sessions of HBO therapy (n=36) or medication treatment (n=32). Pharmacotherapy included antiviral, pain, nerve nutritive and antidepressive medication.

Therapeutic efficacy was calculated at the end of the 3-week treatment period and included the proportion of patients who were healed (i.e., complete subsidence of pain and rash) or improved (i.e., significant pain relief and rash subsistence). Rates of therapeutic efficacy were 97.2% in the HBO group and 81.3% in the medication group. The difference between groups was statistically significant, $p<0.05$. In the HBO group, 22 of 36 patients (61%) were considered to be healed and 13 (36%) were improved. In the medication group, 17 of 32 (53%) patients were healed and 9 (28%) were improved. Limitations of the study include a lack of blinding and lack of long-term follow-up. The evidence from this single RCT is insufficient to draw conclusions about the effect of HBO on health outcomes for patients with herpes zoster; therefore, HBO is considered investigational for this indication.

Clinical Input Received through Physician Medical Societies and Academic Medical Centers

In response to requests, input was received through 6 Physician Specialty Societies and 5 Academic Medical Centers while this policy was under review in 2010. 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. The clinical input was variable depending on the condition. There was universal agreement that topical hyperbaric therapy and systemic hyperbaric oxygen therapy for autism spectrum disorders and headache/migraine are investigational. There was also wide support for changing 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 hyperbaric oxygen treatment. Several reviewers acknowledged that there is a paucity of clinical trials on hyperbaric oxygen treatment 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 hyperbaric oxygen therapy. 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

In 2011, the Undersea and Hyperbaric Medical Society (UHMS) updated their list of indications considered appropriate for hyperbaric oxygen therapy. (64) These indications are as follows:

- Air or gas embolism
- Carbon monoxide poisoning and carbon monoxide complicated by cyanide poisoning
- Clostridial myositis and myonecrosis (gas gangrene)
- Crush injury, compartment syndrome, and other acute traumatic ischemias
- Decompression sickness
- Arterial insufficiencies
    - Central retinal artery occlusion
    - Enhancement of healing in selected problem wounds

- Severe anemia
- Intracranial abscess
- Necrotizing soft tissue infections
- Osteomyelitis (refractory)
- Delayed radiation injury (soft tissue and bony necrosis)
- Skin grafts and flaps (compromised)
- Acute thermal burn injury
- Idiopathic sudden sensorineural hearing loss (ISSNHL) (patients with moderate to profound ISSNHL who present within 14 days of symptom onset)

In 2012, the American Academy of Otolaryngology-Head and Neck Surgery published a clinical guideline on treatment of sudden hearing loss. (65) The guideline includes a statement that HBO may be considered a treatment option for patients who present within 3 months of a diagnosis of idiopathic sudden sensorineural hearing loss. The document states, "Although HBOT is not widely available in the United States and is not recognized by many U.S. clinicians as an intervention for ISSNHL, the panel felt that the level of evidence for hearing improvement, albeit modest and imprecise, was sufficient to promote greater awareness of HBOT as an intervention for [this condition]"

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

CPT/HCPCS

99183	Physician attendance and supervision of hyperbaric oxygen therapy, per session
A4575	Topical hyperbaric oxygen chamber, disposable
C1300	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval

- Topical Hyperbaric Oxygen
  HCPCS code A4575 is used to describe the disposable appliance that is positioned around the wound area. Conventional oxygen tanks, typically gas, are used to supply the oxygen.

Diagnosis

039.0-039.9	Actinomycotic infection (code range)
040.0	Gas gangrene
111.0-111.9	Dermatomycosis, other and unspecified (code range)
112.0-112.3	Candidiasis (code range)
117.7	Zygomycosis [Phycomycosis or Mucormycosis]
117.9	Other and unspecified mycoses
249.00-249.91	Secondary diabetes (code range)

250.00-250.93	Diabetes mellitus (code range)
285.1	Acute posthemorrhagic anemia
324.0	Intracranial abscess
362.31	Central retinal artery occlusion
383.20-383.22	Petrositis (code range)
443.89	Other specified peripheral vascular diseases; other
443.9	Peripheral vascular disease, unspecified
444.21	Arterial embolism and thrombosis of arteries of the extremities; upper extremity
444.22	Arterial embolism and thrombosis of arteries of the extremities; lower extremity
444.81	Arterial embolism and thrombosis of other specified artery; iliac artery
459.9	Unspecified circulatory system disorder
526.4	Inflammatory conditions
526.89	Other specified diseases of the jaws
595.82	Irradiation cystitis
686.00-686.9	Other local infections of skin and subcutaneous tissue (code range)
707.00-707.9	Chronic ulcer of skin (code range)
728.86	Necrotizing fasciitis
728.9	Unspecified disorder of muscle, ligament, and fascia
729.71-729.79	Nontraumatic compartment syndrome (code range)
730.10-730.19	Chronic osteomyelitis (code range)
730.80-730.89	Other infections involving bone in diseases classsified elsewhere (code range)
902.53	Injury to blood vessels of abdomen and pelvis; iliac artery
903.01-903.9	Injury to blood vessels of upper extremity; axillary artery (code range)
904.0	Injury to blood vessels of lower extremity and unspecified sites; common femoral artery
904.1	Superficial femoral artery
904.41	Injury to blood vessels of lower extremity and unspecified sites; popliteal artery
904.51	Anterior tibial artery
904.53	Posterior tibial artery
904.6-904.9	Injury to blood vessels of lower extremity and unspecified sites (code range)
906.0-906.1	Late effects of injuries to skin and subcutaneous tissues (code range)
906.4	Late effect of crushing
909.2	Late effect of radiation
925.1	Crushing injury of face and scalp
925.2	Crushing injury of neck
926.0-926.9	Crushing injury of trunk (code range)

927.0-927.9	Crushing injury of upper arm (code range)
928.00-928.9	Crushing injury of lower limb (code range)
929.0	Crushing injury of multiple sites, not elsewhere classfied
929.9	Crushing injury of unspecified site
941.20-941.29	Blisters, epidermal loss [second degree] (code range)
941.30-941.39	Full-thickness skin loss [third degree NOS] (code range)
941.40-941.49	Deep necrosis of underlying tissues [deep third degree] without mention of loss of a body part (code range)
941.50-941.59	Deep necrosis of underlying tissues [deep third degree] with loss of a body part (code range)
942.20-942.29	Blisters, epidermal loss [second degree] (code range)
942.30-942.39	Full-thickness skin loss [third degree NOS] (code range)
942.40-942.49	Deep necrosis of underlying tissues [deep third degree] without mention of loss of a body part (code range)
942.50-942.59	Deep necrosis of underlying tissues [deep third degree] with loss of a body part (code range)
943.20-943.29	Blisters, epidermal loss [second degree] (code range)
943.30-943.39	Full-thickness skin loss [third degree NOS] (code range)
943.40-943.49	Deep necrosis of underlying tissues [deep third degree] without mention of loss of a body part (code range)
943.50-943.59	Deep necrosis of underlying tissues [deep third degree] with loss of a body part (code range)
944.20-944.28	Blisters, epidermal loss [second degree] (code range)
944.30-944.38	Full-thickness skin loss [third degree NOS]
944.40-944.48	Deep necrosis of underlying tissues [deep third degree] without mention of loss of a body part (code range)
944.50-944.58	Deep necrosis of underlying tissues [deep third degree] with loss of a body part (code range)
945.20-945.29	Blisters, epidermal loss [second degree] (code range)
945.30-945.39	Full-thickness skin loss [third degree NOS] (code range)
945.40-945.49	Deep necrosis of underlying tissues [deep third degree] without mention of loss of a body part (code range)
945.50-945.59	Deep necrosis of underlying tissues [deep third degree] with loss of a body part (code range)
946.2-946.5	Burns of multiple specified sites (code range)

948.00-948.99	Burns classified according to extent of body surface involved (code range)
949.2-949.5	Burn, unspecified (code range)
958.0	Certain early complications of trauma; air embolism
958.8	Other early complications of trauma
958.90-958.99	Traumatic compartment syndrome (code range)
986	Toxic effect of carbon monoxide
987.7	Toxic effect of hydrocyanic acid gas
989.0	Toxic effect of other substances; hydrocyanic acid and cyanides
990	Effects of radiation, unspecified
993.2	Effects of air pressure; other and unspecified effects of high altitude
993.3	Caisson disease
996.52	Mechanical complication of other specified prosthetic devices, implant, and graft; due to graft of other tissue, not elsewhere classified
996.90-996.99	Complications of reattached exterminty or body part (code range)
998.83	Non-healing surgical wound
999.1	Complications of medical care; air embolism

ICD-10 Diagnosis *(Effective October 1, 2014)*

A18.01	B37.49	E08.319	E08.628	E09.359	E09.9
A18.03	B37.83	E08.321	E08.630	E09.36	E10.10
A42.0	B46.0	E08.329	E08.638	E09.39	E10.11
A42.1	B46.1	E08.331	E08.641	E09.40	E10.21
A42.2	B46.2	E08.339	E08.649	E09.41	E10.22
A42.81	B46.3	E08.341	E08.65	E09.42	E10.29
A42.82	B46.4	E08.349	E08.69	E09.43	E10.311
A42.89	B46.5	E08.351	E08.8	E09.44	E10.319
A42.9	B46.8	E08.359	E08.9	E09.49	E10.321
A43.0	B46.9	E08.36	E09.00	E09.51	E10.329
A43.1	B47.1	E08.39	E09.01	E09.52	E10.331
A43.8	B47.9	E08.40	E09.10	E09.59	E10.339
A43.9	B48.3	E08.41	E09.11	E09.610	E10.341
A48.0	B48.8	E08.42	E09.21	E09.618	E10.349
B36.0	B49	E08.43	E09.22	E09.620	E10.351
B36.1	B78.1	E08.44	E09.29	E09.621	E10.359
B36.2	D62	E08.49	E09.311	E09.622	E10.36
B36.3	E08.00	E08.51	E09.319	E09.628	E10.39
B36.8	E08.01	E08.52	E09.321	E09.630	E10.40
B36.9	E08.10	E08.59	E09.329	E09.638	E10.41
B37.0	E08.11	E08.610	E09.331	E09.641	E10.42
B37.2	E08.21	E08.618	E09.339	E09.649	E10.43
B37.3	E08.22	E08.620	E09.341	E09.65	E10.44
B37.41	E08.29	E08.621	E09.349	E09.69	E10.49
B37.42	E08.311	E08.622	E09.351	E09.8	E10.51

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T57.3x4A

T57.3x4D	T58.14xA	T58.8x3S	T65.0x3D	T79.9xxA	T79.A9xS
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T58.02xA	T58.2x1S	T58.91xD	T66.xxxA	T79.A0xS	T81.89xD
T58.02xD	T58.2x2A	T58.91xS	T66.xxxD	T79.A11A	T81.89xS
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T58.04xA	T58.2x3S	T58.93xD	T70.29xA	T79.A12S	T86.829
T58.04xD	T58.2x4A	T58.93xS	T70.29xD	T79.A21A	T87.0x1
T58.04xS	T58.2x4D	T58.94xA	T70.29xS	T79.A21D	T87.0x2
T58.11xA	T58.2x4S	T58.94xD	T70.3xxA	T79.A21S	T87.0x9
T58.11xD	T58.8x1A	T58.94xS	T70.3xxD	T79.A22A	T87.1x1
T58.11xS	T58.8x1D	T65.0x1A	T70.3xxS	T79.A22D	T87.1x2
T58.12xA	T58.8x1S	T65.0x1D	T79.0xxA	T79.A22S	T87.1x9
T58.12xD	T58.8x2A	T65.0x1S	T79.0xxD	T79.A3xA	T87.2
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T58.13xD	T58.8x3A	T65.0x2S	T79.8xxD	T79.A9xA	
T58.13xS	T58.8x3D	T65.0x3A	T79.8xxS	T79.A9xD	

REVISIONS

03-14-2011	Description section updated
	In Policy section: ▪ Revised policy to current policy language from: "Covered Conditions: Benefits are available for hyperbaric oxygen (HBO) therapy that is administered in a chamber (whole body - single or multiple chamber). 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 for the following conditions: 1. Acute carbon monoxide poisoning (986); smoke inhalation (987.9); cyanide poisoning (987.7 and 989.0). 2. Decompression sickness (993.2 – 993.3). 3. Cerebral arterial gas embolism (958.0 and 999.1). 4. Clostridial gas gangrene (040.0). 5. Acute traumatic peripheral ischemia (902.53, 903.01, 903.1, 904.0 and 904.41). 6. Crush injuries and suturing of severed limbs (925.1 - 929.9, 996.90 – 996.99). 7. Pyoderma gangrenosum (686.01) Note: The use of hyperbaric oxygen in any other type of cutaneous ulcer is not covered (problem wounds may be submitted for individual consideration). 8. Osteoradionecrosis as an adjunct to conventional treatment/osteoradionecrosis prevention and prophylactic treatments prior to dental extraction(s) involving

	areas of previously irradiated bone (526.89). 9. Soft tissue radionecrosis as an adjunct to conventional treatment (990). 10. Acute peripheral arterial insufficiency (444.21, 444.22, 444.81). 11. Preparation and preservation of compromised skin grafts (996.52). 12. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management (730.00 – 730.29, 730.80 – 730.89). 13. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment (039.0 – 039.4, 039.8 – 039.9). Conditions for Review: 1. Selected problem wounds 2. Anaerobic septicemia (038.3) and infection other than clostridial (nonclostridial g 3. Acute thermal burns/radiation tissue injury (940 – 949). Conditions Not Medically Necessary: All other diagnosis not previously listed. Conditions Experimental/Investigational: 1. Multiple Sclerosis (340) 2. Topical Application of Oxygen (THBO) -- does not meet the definition of hyperbaric oxygen therapy as stated above. Also, its clinical efficacy has not been established. Therefore, use of topical oxygen is investigational and therefore non-covered. 3. Claims for Partial Body Hyperbaric Oxygen Therapy should be denied as investigational and therefore non-covered."
	Rationale section added
	In Coding section: ▪ Removed HCPCS Code: G0167 ▪ Added HCPCS Code: A4575 ▪ Removed Diagnosis Codes: 686.01, 987.9 ▪ Added Diagnosis Codes: 111.0-111.9, 112.0-112.3, 117.7, 117.9, 249.00-250.93, 285.1, 324.0, 362.31, 383.20-383.22, 443.89, 443.9, 459.9, 526.4, 595.82, 686.00-686.9, 707.00-707.19, 707.20-707.25, 707.8-707.9, 728.86, 728.9, 729.71-729.79, 903.01-903.9, 904.1, 904.51, 904.53, 904.6-904.9, 906.0-906.1, 906.4, 909.2, 941.20-941.59, 942.20-942.59, 943.20-943.59, 944.20-944.58, 945.20-945.59, 946.2-946.5, 948.00-948.99, 949.2-949.5, 958.8, 958.90-958.99, 998.83
	References section updated
10-11-11	In the Policy title, removed "(HBO2) Therapy" and inserted "Pressurization (HBO)" to read "Hyperbaric Oxygen Pressurization (HBO)"
	Updated the Description section.
	In the Policy section: • In Item A, #5, removed "(CRAO)" • In Item C, removed "all other conditions" and inserted "the following conditions" • In Item C, added the following conditions: 1. " acute osteomyelitis, refractory to standard medical management; 2. acute surgical and traumatic wounds; 3. spinal cord injury; 4. traumatic brain injury;

	5. severe or refractory Crohn's disease;
	6. acute brown recluse spider bites; 7. bone grafts; 8. carbon tetrachloride poisoning, acute; 9. cerebrovascular disease, acute (thrombotic or embolic) or chronic; 10. fracture healing; 11. hydrogen sulfide poisoning; 12. intra-abdominal abscesses; 13. lepromatous leprosy; 14. meningitis; 15. Pseudomembranous colitis (antimicrobial agent-induced colitis); 16. radiation myelitis; 17. sickle cell crisis and/or hematuria; 18. demyelinating diseases, e.g., multiple sclerosis, amyotrophic lateral sclerosis; 19. retinopathy, adjunct to scleral buckling procedures in patients with sickle cell peripheral retinopathy and retinal detachment; 20. pyoderma gangrenosum; 21. acute coronary syndromes and as an adjunct to coronary interventions, including but not limited to, percutaneous coronary interventions and cardiopulmonary bypass; 22. idiopathic sudden sensorineural hearing loss; 23. refractory mycoses: mucormycosis, actinomycosis, canidiobolus coronato; 24. cerebral edema, acute; 25. migraine; 26. in vitro fertilization; 27. cerebral palsy; 28. tumor sensitization for cancer treatments, including but not limited to, radiotherapy or chemotherapy; 29. delayed onset muscle soreness; 30. idiopathic femoral neck necrosis; 31. chronic arm lymphedema following radiotherapy for cancer; 32. radiation-induced injury in the head and neck; 33. early treatment (beginning at completion of radiation therapy) to reduce adverse effects of radiation therapy; and 34. autism spectrum disorders."
	Updated the Rationale section.
	Updated the References section.
01-01-2012	In the Coding section: ▪ Added HCPCS code A9272
01-30-2012	In the Coding section: ▪ Removed HCPCS code A9272
03-27-2014	In Policy section: ▪ In Item A, #3, added "e.g., crush injuries, reperfusion injury, compartment syndrome" to read "Acute traumatic ischemia (e.g., crush injuries, reperfusion injury, compartment syndrome); or" ▪ In Item A, removed #11, crush injuries was incorporated into Item A, #3.

	▪ In Item C, added #36, "bisphosphonate-related osteonecrosis of the jaw" ▪ In Item C, added #37, "acute ischemic stroke; and" ▪ In Item C, added #38. "Bell's palsy."
	Rationale section updated.
	In Coding section: ▪ Added ICD-10 Diagnosis *(Effective October 1, 2014)*
	Reference section updated.

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