



# Louisiana

## Hyperbaric Oxygen Pressurization (HBO)

**Policy #** 00070

**Original Effective Date:** 08/25/2003

**Current Effective Date:** 12/20/2017

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### **When Services May Be Eligible for Coverage**

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider systemic hyperbaric oxygen pressurization (HBO) when patient selection criteria are met to be **eligible for coverage**.

### Patient Selection Criteria

Coverage eligibility will be considered for the use of systemic hyperbaric oxygen pressurization (HBO) when any of the following indications or criteria are met:

- Acute carbon monoxide poisoning; or
- Decompression sickness; or
- Gas gangrene (i.e., clostridial myonecrosis); or
- Acute osteomyelitis, refractory to standard medical management; or
- Acute traumatic peripheral ischemia: hyperbaric oxygen pressurization 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; or
- Crush injuries and suturing of severed limbs: as in the previous conditions, hyperbaric oxygen pressurization therapy would be an adjunctive treatment when loss of function, limb or life is threatened; or
- Progressive necrotizing infections (necrotizing fasciitis); or
- Acute peripheral arterial insufficiency; or
- Preparation and preservation of compromised skin grafts (not for primary management of wounds); or
- Cyanide poisoning, acute; or
- Radiation necrosis (osteoradionecrosis and soft tissue radiation necrosis [e.g., radiation enteritis, cystitis, proctitis]) as an adjunct to conventional treatment; or
- Profound anemia with exceptional blood loss: only when blood transfusion is impossible or must be delayed; or
- Brown recluse spider bites; or
- Chronic refractory osteomyelitis; or
- Prophylactic pre- and post- treatment for patients undergoing dental surgery of a radiated jaw; or
- Diabetic wounds of the lower extremities in patients who meet the following three criteria:
  - o Patient has type I or II diabetes and has a lower extremity wound due to diabetes;

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- o Patient has a wound classified as Wagner Grade III or higher, The Wagner classification system of wounds is defined as follows:
  - Grade 0 = no open lesion;
  - Grade I = superficial ulcer without penetration to deeper layers;
  - Grade II = ulcer penetrates to tendon, bone, or joint;
  - Grade III = lesion has penetrated deeper than Grade II and there is abscess, osteomyelitis, pyarthrosis, plantar space abscess or infection of the tendon and tendon sheaths;
  - Grade IV = wet or dry gangrene in the toes or forefoot;
  - Grade V = 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; and
- o Patient has failed an adequate course of standard wound therapy.

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

### **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers topical hyperbaric oxygen pressurization (HBO) to be **investigational**.\*

Based on review of available data, the Company considers limb specific hyperbaric oxygen pressurization (HBO) to be **investigational**.\*

Based on review of available data, the Company considers the use of systemic hyperbaric pressurization in the treatment of the following conditions, and all other conditions not noted above, to be **investigational**\*:

- Acute coronary syndromes and as an adjunct to percutaneous coronary interventions, including but not limited to percutaneous coronary interventions and cardiopulmonary bypass; or

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- Acute ischemic stroke; or
- Acute or chronic cerebral vascular insufficiency; or
- Acute surgical and traumatic wounds; or
- Acute thermal and chemical pulmonary damage, i.e. smoke inhalation with pulmonary insufficiency; or
- Aerobic septicemia; or
- Anaerobic septicemia and infection other than clostridial; or
- Arthritic disease; or
- Autism; or
- Bone grafts; or
- Carbon tetrachloride poisoning, acute; or
- Cardiogenic shock; or
- Cerebral edema, acute; or
- Cerebral palsy; or
- Cerebrovascular disease, acute (thrombotic or embolic) or chronic; or
- Chronic arm lymphedema following radiotherapy for cancer; or
- Chronic non-diabetic wounds; or
- Chronic peripheral vascular insufficiency; or
- Cutaneous, decubitus and stasis ulcers; or
- Delayed onset muscle soreness; or
- Demyelinating diseases (e.g., multiple sclerosis, amyotrophic lateral sclerosis); or
- Fracture healing; or
- Fibromyalgia; and
- Hepatic necrosis; or
- Hydrogen sulfide poisoning; or
- Idiopathic femoral neck necrosis; or
- Idiopathic sudden sensorineural hearing loss; or
- Inflammatory bowel disease (Crohn disease or ulcerative colitis); or
- Intra-abdominal and intracranial abscesses; or
- In vitro fertilization; or
- Lepromatous leprosy; or
- Meningitis; or
- Mental illness (ie, posttraumatic stress disorder, generalized anxiety disorder or depression); or
- Migraine; or
- Multiple sclerosis; or
- Myocardial infarction; or
- Nonvascular causes of chronic brain syndrome (Pick's, Alzheimer's and Korsakoff's disease); or
- Organ storage; or
- Organ transplantation; or

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- Pseudomembranous colitis (antimicrobial agent-induced colitis); or
- Pulmonary emphysema; or
- Pyoderma gangrenosum; or
- Radiation-induced injury in the head and neck; or
- Refractory mycoses: mucomycosis, actinomycosis, canidiobolus coronato; or
- Retinopathy, adjunct to scleral buckling procedures in patients with sickle cell peripheral retinopathy and retinal detachment; or
- Senility; or
- Severe or refractory Crohn's disease; or
- Sickle cell crisis and/or hematuria; or
- Skin burns, thermal; or
- Spinal cord injury; or
- Tetanus; or
- Traumatic brain injury; or
- Tumor sensitization for cancer treatments, including but not limited to, radiotherapy or chemotherapy; or
- Bisphosphonate-related osteonecrosis of the jaw; or
- Motor dysfunction associated with stroke; or
- Herpes zoster; or
- Vascular dementia

### **Background/Overview**

HBO therapy involves breathing 100% oxygen at a pressure of more than 1 atmosphere (atm). HBO therapy is generally applied systemically with the patient inside a hyperbaric chamber. It can also be topical; that is, the body part to be treated is isolated, e.g., in an inflatable bag and exposed to pure oxygen. Hyperbaric oxygen therapy has been investigated for various conditions that have potential to respond to increased oxygen delivery to the tissues.

Hyperbaric oxygen pressurization is a technique of delivering higher pressures of oxygen to the tissues. Two methods of administration are available. In systemic or large chamber HBO, the patient is entirely enclosed in a pressure chamber and breathes oxygen at a pressure greater than one atmosphere (the pressure of O<sub>2</sub> at sea level). Thus, this technique relies on the systemic circulation to deliver highly oxygenated blood to the target site, typically a wound. In addition, systemic HBO 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 HBO 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

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oxygen diffuse directly into the wound to increase the local cellular oxygen tension, which in turn promotes wound healing. Topical HBO 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 HBO therapy has been investigated as a treatment of skin ulcerations due to diabetes, venous stasis, post-surgical infection, gangrenous lesion, decubitus ulcers, amputations, skin graft, burns or frostbite.

### **FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

In February 1999, the Numobag™<sup>‡</sup> Kit (Numotech, Inc; Woodland Hills, CA) for application of topical hyperbaric therapy was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices. Another example is the AOTI Hyper-Box™<sup>‡</sup> (AOTI Ltd., Galway, Ireland), which was cleared by FDA in 2008.

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.

In 2013, FDA published a statement warning that non-FDA approved uses of HBOT may endanger the health of patients. If patients mistakenly believe that HBOT devices have been proven safe for uses not cleared by FDA, they may delay or forgo proven medical therapies.

Centers for Medicare and Medicaid Services (CMS)

As of April 1, 2003, the CMS added Medicare coverage of HBO therapy for diabetic wounds of the lower extremities meeting certain criteria. Medicare coverage is provided for HBOT administered in a chamber for the following conditions:

- Acute carbon monoxide intoxication (ICD-9-CM diagnosis 986)
- Decompression illness (ICD-9-CM diagnosis 993.2, 993.3)
- Gas embolism (ICD-9-CM diagnosis 958.0, 999.1)
- Gas gangrene (ICD-9-CM diagnosis 0400)
- Acute traumatic peripheral ischemia. HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened (ICD-9-CM diagnosis 902.53, 903.01, 903.1, 904.0, 904.41).
- Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened (ICD-9-CM diagnosis 927.00-927.03, 927.09-927.11, 927.20-927.21, 927.8-927.9, 928.00-928.01, 928.10-928.11, 928.20-928.21, 928.3, 928.8-928.9, 929.0, 929.9, 996.90- 996.99).
- Progressive necrotizing infections (necrotizing fasciitis) (ICD-9-CM diagnosis 728.86)
- Acute peripheral arterial insufficiency (ICD-9-CM diagnosis 444.21, 444.22, 81)

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- Preparation and preservation of compromised skin grafts (not for primary management of wounds) (ICD-9CM diagnosis 996.52; excludes artificial skin graft)
- Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management (ICD-9-CM diagnosis 730.10-730.19)
- Osteoradionecrosis as an adjunct to conventional treatment (ICD-9-CM diagnosis 526.89)
- Soft tissue radionecrosis as an adjunct to conventional treatment (ICD-9-CM diagnosis 990)
- Cyanide poisoning (ICD-9-CM diagnosis 987.7, 989.0)
- Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment (ICD-9-CM diagnosis 039.0-039.4, 039.8, 039.9)
- Diabetic wounds of the lower extremities in patients who meet the following 3 criteria:
  - o Patient has type I or type II diabetes and has a lower extremity wound that is a result of diabetes;
  - o Patient has a wound classified as Wagner grade III or higher; and
  - o Patient has failed an adequate course of standard wound therapy.

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

Medicare continues to consider topical HBO therapy ineligible for coverage.

*Note: Medicare differs from BCBS policy in that it provides coverage for systemic HBO therapy for acute carbon monoxide intoxication, actinomycosis, acute peripheral arterial insufficiency, compromised skin grafts or flaps, and necrotizing soft tissue infections. However, as noted here, literature searches did not reveal sufficient evidence to consider these appropriate indications for HBO therapy.*

### **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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### **Topical Hyperbaric Oxygen**

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

### **Systemic Hyperbaric Oxygen**

Updated searches of the literature identified no randomized or non-randomized studies on topical HBO. Thus, topical HBO therapy remains investigational.

### *Chronic Wounds*

A Cochrane review of RCTs on HBO treatment for chronic wounds was published by Kranke and colleagues in 2004. The authors reported finding insufficient evidence to demonstrate benefits with use of HBO for arterial, venous, or pressure ulcers or wounds or other pathologies due to limited trial data. However, they found that, in diabetic patients with foot ulcers, HBO significantly reduced the risk of major amputations based on an analysis of 5 trials and concluded that HBO therapy may be justified in this group of patients when appropriate facilities are available. A 2011 double-blind RCT from Sweden evaluated HBO therapy in 75 diabetic patients with chronic wounds who had failed at least 2 months of treatment at a diabetic foot clinic. After 12 months, the healing rate was 61% in the HBO group and 27% in the sham hyperbaric group; this difference was statistically significant,  $p = 0.009$ . This new study supports the findings of the 2004 Cochrane review, which has not been updated. Thus, HBO therapy for chronic severe diabetic ulcers may be considered medically necessary, and HBO treatment for other types of chronic wounds is considered investigational.

In 2013, O'Reilly et al published a systematic review of studies on HBOT for treatment of diabetic ulcers. The authors identified 6 RCTs and 6 non-RCTs that compared HBOT with standard wound care or sham therapy in patients with diabetes who had nonhealing lower-limb ulcers. Pooled analyses of observational studies found statistically significant benefits of HBOT on rates of major amputation, minor amputation, and the proportion of wounds healed at the end of the study period. However, in pooled analyses of RCT data, the stronger study design, there were no statistically significant differences between groups on key outcomes. This included the rate of major amputation (RR=0.40; 95% CI, 0.07 to 2.23;  $p=0.29$ ), minor amputation (RR=0.79; 95% CI, 0.19 to 3.30,  $p=0.75$ ), and the proportion of unhealed wounds at the end of the study period (RR=0.54, 95% CI, 0.26 to 1.13,  $p=0.1$ ).

Systematic reviews have had mixed findings on the impact of HBOT on diabetic ulcers. A Cochrane review found short-term, but not long-term benefit on wound healing, and a 2013 meta-analysis did not find significant benefits of HBOT on outcomes in RCTs, but did find an effect in non-RCTs. There is insufficient evidence on HBOT for treatment of chronic wounds in patients without diabetes.

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### *Acute surgical and traumatic wounds*

In 2013, an updated Cochrane review of RCTs on HBOT for acute surgical and traumatic wounds was published by Eskes et al. HBOT was defined as use of 100% oxygen at pressures above 1 atm. To be included, studies needed to compare HBOT with a different intervention or compare 2 HBOT regimens; in addition, studies needed to objectively measure wound healing. A total of 4 met the review's inclusion criteria. The studies ranged in size from 10 to 135 participants. Due to differences among studies in terms of patient population, comparison intervention, and outcome measurement, study results could not be pooled. The primary outcome examined by Cochrane reviewers, wound healing, was not reported in either of the 2 trials comparing HBOT with usual care and was not reported in the 1 trial comparing HBOT with dexamethasone or heparin. Complete wound healing was reported in the RCT comparing active HBOT with sham HBOT. In this small study (N=36), there was a statistically higher rate of wound healing in the group; the time point for outcome measurement in this study was unclear. In the sham-controlled study, there was no statistically significant difference between groups in the meantime to wound healing.

Another 2014 systematic review of studies on HBOT for acute wounds, published by Dauwe et al, included RCTs and non-RCTs. The review included 8 studies, with sample sizes ranging from 5 to 125 patients. Four studies were randomized, 3 were prospective non-RCTs, and 1 was a retrospective non-RCT. As in the Eskes systematic review, data were not pooled. The authors noted that 7 of the 8 studies reported achieving statistical significance in their primary end points, but the end points differed among studies (eg, graft survival, length of hospital stay, wound size). Moreover, the studies were heterogeneous in terms of treatment regimens, patient indications (eg, burns, face lifts), and study designs, making it difficult to draw conclusions about the effect of HBOT on acute wound treatment.

There is insufficient evidence supporting HBOT for treatment of acute wounds; additional evidence from high-quality RCTs is needed.

### *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. In 2008, the American College of Emergency Physicians published a clinical policy on critical issues in carbon monoxide poisoning. 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. The authors reported that HBO therapy did not benefit patient outcomes of neuropsychological 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 administering 100% normobaric oxygen for at least 72

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hours between treatments which has been called a toxic dose of oxygen. 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. 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. 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 the use of HBO therapy for acute carbon monoxide poisoning is eligible for coverage.

### *Radionecrosis and Osteoradionecrosis*

Several systematic reviews of RCTs have been published. A 2008 Cochrane review by Esposito et al reviewed the use of HBOT 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 HBOT in irradiated patients requiring dental implants may not offer any appreciable clinical benefits. They indicated that there is a need for more RCTs to ascertain the effectiveness of HBOT in irradiated patients requiring dental implants.

In 2012, Bennett et al published a Cochrane review on HBOT for late radiation tissue injury. 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 HBOT compared with controls (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, [HBOT] is associated with improved outcome. HBOT 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.”

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HBOT has long been used to treat soft tissue and bone radiation necrosis and for pre- and posttreatment of dental surgery (non-implant-related) in an irradiated jaw.

### *Bisphosphonate-Related Osteonecrosis of the Jaw*

An unblinded RCT was published by Freiburger et al in 2012 on use of HBOT as an adjunct therapy for patients with bisphosphonate-related osteonecrosis of the jaw. Forty-nine patients were randomly assigned to HBOT in addition to standard care (n=22) or standard care alone (n=27). Five patients in the standard care group received HBOT and 1 patient assigned to the HBOT group declined HBOT. The investigators did 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 HBOT 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 HBOT-treated patients had improvement in oral lesion size or number compared with 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 no 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 (eg, unblinded, crossover, 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 2 groups may differ on characteristics that affect outcomes. As a result, this trial is insufficient to conclude that HBOT 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 based primarily 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. 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. 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. 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, the use of HBO therapy for chronic refractory osteomyelitis was changed to be eligible for coverage.

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### *Fracture Healing*

In 2012, Bennett et al published a Cochrane review on HBOT to promote fracture healing and treat nonunion fractures. The investigators did not identify any published RCTs on this topic that compared HBOT with no treatment, sham, or another intervention and reported bony union as an outcome.

### *Compromised Skin Grafts and Flaps*

In 2006, Friedman et al published a systematic review of literature on use of HBOT for treating skin flaps and grafts. No RCTs were found. The authors identified 2 retrospective case series on use of HBOT 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.

### *Necrotizing Soft Tissue Infections*

A 2015 Cochrane review by Levett et al evaluated the literature on HBOT as adjunctive therapy for necrotizing fasciitis. No RCTs were identified. Previously, in 2005, a systematic review by Jallali et al identified only a few retrospective studies with small sample sizes. Findings of these studies were inconsistent. A 2009 retrospective cohort study compared outcomes in 48 patients at 1 center who received adjunctive HBOT for necrotizing soft tissue infections with those in 30 patients at a different center who did not receive HBO. There was no significant difference in the mortality rate between the 2 groups (4/48 [8%]) in the HBOT group, 4/30 [13%] in the non-HBOT 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 débridement procedures per person in the HBOT group (3.0) than in the non-HBOT group (2.0) ( $p=0.03$ ).

### *Refractory Mycoses*

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

### *Acute Peripheral Arterial Insufficiency*

Medicare has long listed acute peripheral arterial insufficiency as a medically necessary indication.

### *Acute Coronary Syndromes*

A 2011 Cochrane review by Bennett and colleagues identified 6 trials with a total of 665 patients concluded there were no significant benefits for patients with acute coronary syndromes receiving HBO therapy. All studies included patients with acute myocardial infarction (MI); 1 study also included individuals presenting with unstable angina. Additionally, all trials used HBOT 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 HBOT compared with a control intervention (RR=0.58; 95% CI, 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 HBOT (RR=0.09; 95% CI, 0.01 to 1.4). The authors noted that, although there is some evidence from small trials

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that HBOT is associated with a lower risk of death, larger trials with high-quality methods are needed to determine which patients, if any, can be expected to derive benefit from HBOT.

One trial was by Sharifi and colleagues and randomly assigned 69 patients with unstable angina or acute myocardial infarction to receive or not receive HBO after a percutaneous coronary intervention (PCI). The 24 patients randomly assigned 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 lacked adequate detail, e.g., on the type of PCI performed, to permit scientific conclusions. In another randomized, controlled trial of 64 patients, Alex and colleagues concluded both neuropsychometric dysfunction and inflammatory response can be reduced postcardiopulmonary bypass when HBO pretreatment is given.

### *Acute Ischemic Stroke*

All studies included patients with acute myocardial infarction (MI); 1 study also included individuals presenting with unstable angina. Additionally, all trials used HBOT 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 HBOT compared with a control intervention (RR=0.58; 95% CI, 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 HBOT (RR=0.09; 95% CI, 0.01 to 1.4). The authors noted that, although there is some evidence from small trials that HBOT is associated with a lower risk of death, larger trials with high-quality methods are needed to determine which patients, if any, can be expected to derive benefit from HBOT.

### *Motor Dysfunction Associated With Stroke*

In 2013, Efrati et al published an RCT evaluating HBOT for treatment of neurologic deficiencies associated with a history of stroke. The study included 74 patients with at least 1 motor dysfunction who had an ischemic or hemorrhagic stroke 6 to 36 months prior to study participation. Participants were randomly assigned to receive 2 months of HBOT (40 daily sessions, 5 d/wk, 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 HBOT. 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 (QOL) and functional status measures.

At 2-month follow-up, there was statistically significantly greater improvement in function in the HBOT group than in the control group, as measured by NIHSS, QOL 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 imaging in the regions affected by stroke. For the delayed treatment control group, there was a statistically significant improvement in function after HBOT than before HBOT. This RCT raises the possibility that HBOT may induce improvements in function and QOL for

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poststroke 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 poststroke patients. The study was not double-blind and most outcome measures, except for 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.

### *Bell Palsy*

In 2012, Holland et al published a Cochrane systematic review evaluating HBOT in adults with Bell palsy. The authors identified 1 RCT with 79 participants, and this study did not meet the Cochrane review's methodologic standards because the outcome assessor was not blinded to treatment allocation.

### *Traumatic Brain Injury*

A 2012 Cochrane systematic review addressed HBOT as adjunctive therapy for traumatic brain injury. The investigators identified 7 RCTs with a total of 571 participants comparing a standard intensive treatment regimen with the same treatment regimen plus HBOT. The review did not include studies in which interventions occurred in a specialized acute care setting. The HBOT regimens varied among studies; eg, the total number of individual sessions varied from 3 to between 30 and 40. None of the trials in the review used sham treatment or blinded the staff members treating patients, and only 1 had blinding of outcome assessment. Allocation concealment was inadequate in all 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 HBOT 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 was not statistically significant (RR=0.71; 95% CI, 0.50 to 1.01). Unfavorable outcome was commonly defined as a Glasgow Outcome Scale score of 1, 2, or 3, which are described as "dead," "vegetative state," or "severely disabled," respectively. Studies were generally small and judged to have substantial risk of bias.

Several trials on mild traumatic brain injury in military populations have been published and they did not find significant benefits of HBOT compared with sham treatment. The first trial, published by Wolf et al in 2012, included 50 military service members, 48 of whom were male, with combat-related mild traumatic brain injury. Participants were randomized to 30 sessions of HBOT over 8 weeks (n=25) or a sham intervention (room air at 1.3 atmosphere, absolute [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 HBOT 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.

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A 2014 double-blind sham-controlled trial 2014 RCT by Cifu et al included 61 male Marines who had a history of mild traumatic brain injury and postconcussive syndrome. To maintain blinding, all patients were pressured inside a hyperbaric chamber to 2.0 ata. They were randomized to breathe 1 of 3 oxygen-nitrogen gas mixes equivalent to: (1) 75% oxygen at 1.5 ata (n=21); (2) 100% oxygen at 2.0 ata (n=19); and (3) sham treatment with surface room air (n=21). Patients underwent 40 once-daily 60-minute sessions. Outcomes were assessed 3 months after the last exposure. The primary outcome was a clinically meaningful improvement, defined as a 10% difference between groups in the score on the 16-item Rivermead Post-Concussion Questionnaire (RPQ; (scale range, 50-84; higher values indicate more severe symptoms). At follow-up, there was no statistically significant difference among groups on RPQ-16 score (p=0.41). A variety of secondary outcomes were also assessed. None, including measures of attention, cognition, or depression, differed significantly among groups at follow-up.

In 2015, Miller et al evaluated HBOT in 72 military service members with continuing symptoms at least 4 months after mild traumatic brain injury. Patients were randomized to receive 40 daily HBOT sessions at 1.5 ata, 40 sham sessions consisting of room air at 1.2 ata, or standard care with no hyperbaric chamber sessions. The primary outcome was change in RPQ score. A cutoff of 15% improvement was deemed clinically important, which translates to a change score of at least 2 points on the RPQ-3 subscale. The proportion of patients who met the prespecified change of at least 2 points on the RPQ-3 was 52% in the HBOT group, 33% in the sham group, and 25% in the standard care-only group. The difference between rates in the HBOT and sham groups was not statistically significant (p=0.24). None of the secondary outcomes significantly favored the HBOT group. A criticism of this study, as well as the other military population studies, was that the response in the sham group was not due to a placebo effect but to an intervention effect of slightly increased atmospheric pressure (1.2 ata). Other researchers have noted that room air delivered at 1.2 ata would not be considered an acceptable therapeutic dose for any indication, and especially for a condition with persistent symptoms like post concussive syndrome.

### *Inflammatory Bowel Disease*

A 2014 systematic review by Dulai et al examined the evidence on HBOT for inflammatory bowel disease (Crohn disease and ulcerative colitis). The review was not limited by study design. The authors included 17 studies: 1 RCT, 2 case-control studies, 3 case series, and 11 case reports. The studies reported on a total of 613 patients, 286 with Crohn disease and 327 with ulcerative colitis. The only RCT identified was published in 2013; it was open-label and included 18 patients with ulcerative colitis. Patients were randomized to treatment with standard medical therapy only (n=8) or medical therapy plus HBOT (n=10). The hyperbaric oxygen intervention consisted of 90 minutes of treatment at 2.4 atm, 5 days a week for 6 weeks (total of 30 sessions). The primary outcome was the Mayo score, which has a potential range of 0 to 12. Patients with a score of 6 or more are considered to have moderate-to-severe active disease. At follow-up, there was no significant difference between groups in the Mayo score; the median score at 6 months was 0.5 in the HBOT group and 3 in the control group (p value not reported). In addition, there were no significant differences in any of the secondary outcomes, including laboratory tests and fecal weight. This is a small study that may have been underpowered. Overall, the authors found that the studies had a high risk of bias, particularly in the areas of attrition and reporting bias.

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In summary, there is insufficient evidence that HBOT is effective for treating inflammatory bowel disease. Only 1 small RCT has been published, and this study did not find a significant improvement in health outcomes when HBOT was added to standard medical therapy.

### *Idiopathic Sudden Sensorineural Hearing Loss*

In 2011, UHMS added idiopathic sudden sensorineural hearing loss (ISSNHL) within the past 14 days as an approved indication for HBOT.

A 2012 Cochrane review on HBOT for ISSNHL and tinnitus identified 7 RCTs with a total of 392 participants. 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 1 study, and only 1 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 (eg, the total number of treatment sessions varied from 10-25).

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 HBOT and the 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 HBOT than 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 HBOT compared with control (mean difference, 15.6 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 HBOT for treating ISSNHL.

In 2013, Cvorovic et al published an RCT that included 50 patients with ISSNHL who had failed primary therapy with intravenous steroids. Patients were randomized to receive HBOT (20 sessions, 5 daily sessions per week) or intratympanic steroid injection (4 injections in 13 days). The HBOT sessions consisted of 10 minutes of compression on air, 60 minutes of 100% oxygen at 2 ata, and 10 minutes of decompression on air. Outcomes were change in the mean hearing thresholds at each of 5 frequencies (0.25, 0.5, 1, 2, and 4 kHz). After treatment, there were no statistically significant differences in mean hearing thresholds at 4 of the 5 frequencies. The exception was 2 kHz, and at that frequency, the improvement was significantly greater in the HBOT group.

Due to methodologic limitations and variability among published studies, as well as inconsistent findings, the evidence is insufficient to draw conclusions about the effect of HBOT on health outcomes in patients with ISSNHL.

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### *Cancer Treatment*

In an RCT of 32 patients, Heys et al found no increase in 5-year survival in patients treated with HBOT prior to chemotherapy for locally advanced breast carcinoma to increase tumor vascularity. This approach is being studied because studies in animal models have suggested that HBOT increases tumor vascularity and thus may make chemotherapy more effective. In a Cochrane review, Bennett et al concluded that HBOT given with radiotherapy may be useful in tumor control; however, the authors expressed caution because significant adverse effects were common with HBOT and indicated further study would be useful.

### *In Vitro Fertilization*

Van Voorhis et al reported that HBOT was well-tolerated in women undergoing ovarian follicular stimulation for in vitro fertilization; however, no outcomes were reported, and further study is needed.

### *Delayed-Onset Muscle Soreness*

In a Cochrane review, Bennett et al concluded that available evidence is insufficient to demonstrate beneficial outcomes with HBOT for delayed-onset muscle soreness and closed soft tissue injury. It was noted that HBOT possibly increases pain initially and further studies are needed.

### *Autism Spectrum Disorder*

A 2012 systematic review of evidence on HBOT for treatment of children with autism identified 2 RCTs with a total of 89 participants. One of the 2 RCTs found better outcomes after HBOT compared with 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 to draw conclusions about the efficacy of HBOT for treating autism.

A key RCT was by Rossignol et al. This double-blind trial included 62 children, ages 2 to 7 years, who met Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, criteria for autistic disorder. The active treatment was hyperbaric treatment at 1.3 atm and 24% oxygen in a hyperbaric chamber. (This regimen differs from standard HBOT, 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 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 versus 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 less than 0.05 were considered statistically significant; there was no adjustment for

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multiple comparisons. The analysis included all children who completed at least 1 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 with the control group, the treatment group had a significant improvement in 1 of 4 ATEC subscales, 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 1 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 of 30 (30%) children in the treatment group had a score of 1 (very much improved) or 2 (much improved) compared with 2 of 26 (8%) in the control group ( $p=0.047$ ). On the parental-rated CGI total score, 9 of 30 (30%) children in the treatment group had a score of 1 or 2 compared with 4 of 26 (15%) in the control group ( $p=0.22$ , not statistically significant). (The exact numbers receiving scores of 1 versus 2 were not reported.) Change in mean CGI scores was 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 than controls on 2 of 18 subscales, Receptive Language ( $p=0.017$ ) and Eye Contact ( $p=0.032$ ).

A limitation of this study is that the authors reported only outcomes at 4 weeks, directly after completion of the intervention. It is not known whether there were 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. UHMS issued a position paper after publication of the Rossignol et al study stating that it still did not recommend routine HBOT for autism.

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

### *Amyotrophic Lateral Sclerosis*

No randomized trials were found evaluating HBOT for treatment of amyotrophic lateral sclerosis. In a small case series, Steele et al treated 5 patients with HBOT and reported some improvements in fatigue but noted that further study is needed, with attention to placebo effects.

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### *Cerebral Palsy*

Two published RCTs were identified on HBOT for cerebral palsy. In 2012, Lacey et al published a double-blind RCT that included 49 children age 3 to 8 years with spastic cerebral palsy. Participants were randomized to receive 40 treatments with either HBOT (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 interim analysis, the posttreatment GMFM-88 global score was a mean (SD) of 40.8 (33.4) in the HBOT group and 41.2 (29.6) in the hyperbaric air group (p=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 HBOT (n=57) or slightly pressurized room air (n=54).<sup>59</sup> The authors found HBOT produced similar improvements in outcomes such as gross motor function and ADLs in both groups as slightly pressurized air. The available evidence does not support HBOT for cerebral palsy.

### *Vascular Dementia*

A 2012 Cochrane review identified 1 RCT evaluating HBOT for vascular dementia. The 2009 RCT study, conducted in China, compared HBOT plus donepezil with donepezil-only in 64 patients. The HBOT plus 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 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 HBOT on vascular dementia.

### *Radiotherapy Adverse Effects*

In 2010, Spiegelberg et al conducted a systematic review of studies on HBOT to prevent or treat radiotherapy-induced head and neck injuries associated with treatment of malignant tumors. The authors identified 20 studies. Eight studies included control groups; their sample sizes ranged from 19 to 78 subjects. Four studies with a control group concluded that HBOT was effective, and the other 4 did not. The authors noted a paucity of RCTs; they did not state how many RCTs they identified in their review.

A study by Teguh et al published in 2009 included 17 patients with oropharyngeal or nasopharyngeal cancer who were treated with radiotherapy; the study was conducted in The Netherlands. HBOT was used to prevent adverse events following radiotherapy. Eight patients were randomly assigned to receive 30 sessions of HBOT, beginning within 2 days of completing radiotherapy, and 9 patients received no additional treatment. All patients were included in the analysis. QOL outcomes were assessed, and the primary outcome was specified as xerostomia at 1 year. QOL 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 HBOT 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 HBOT group and 7 in the control group (p=0.002). Also at 1 year, the mean QOL

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score for swallowing (0-to-100 scale) was 7 in the HBOT group and 40 in the control group ( $p < 0.001$ ). The study is limited by the small sample size and the wide fluctuation over the follow-up period in QOL ratings.

In 2010, Gothard et al in the U.K. published findings of an RCT using HBOT for arm lymphedema occurring after radiotherapy for cancer. 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 HBOT ( $n=38$ ) or usual care without HBOT ( $n=20$ ). Fifty-three patients had baseline assessments and 46 of 58 (79%) had 12-month assessments. At the 12-month follow-up, there was no 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 HBOT group were considered responders compared with 3 of 16 (19%) in the control group; the difference between groups was not statistically significant. Other outcomes (eg, QOL scores on the 36-Item Short-Form Health Survey [SF-36]) were similar between groups.

There are limited data on the use of HBOT in patients with arm lymphedema or radiation-induced injury in the head and neck after radiotherapy and on early use of HBOT after radiotherapy to reduce adverse effects.

### *Idiopathic Femoral Neck Necrosis*

A double-blind RCT that evaluated HBOT to treat femoral head necrosis was published in 2010 by Camporesi et al. The study included 20 adult patients with idiopathic unilateral femoral head necrosis. Patients received 30 treatments over 6 weeks with either HBOT 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 HBOT 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. At the end of the initial treatment period, extension, abduction, and adduction, but not flexion, were significantly greater in the HBOT group than in the control group. Longer term comparative data were not available because the control group was offered HBOT 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 HBOT for femoral head necrosis.

### *Migraine*

A 2008 Cochrane review by Bennett et al identified RCTs that evaluated the effectiveness of systemic HBOT for preventing or treating migraine headache compared with another treatment or a sham control. 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 HBOT. A pooled analysis of 3 trials (total  $N=43$  patients) found a statistically significant increase in the proportion of patients with substantial relief of migraine within 45 minutes of HBOT (RR=5.97; 95% CI, 1.46 to 24.38;  $p=0.001$ ). No other pooled analyses were conducted due to variability in the outcomes reported in the trials. The meta-analysis does not report data on treatment

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effectiveness beyond the immediate posttreatment period, and the quality of trials' methodology was moderate to low (eg, randomization was not well-described in any trial).

### *Herpes Zoster*

In 2012, Peng et al in China published an RCT evaluating HBOT for herpes zoster. Sixty-eight patients with herpes zoster diagnosed within the previous 2 weeks were randomized to 30 sessions of HBOT (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 (ie, complete subsidence of pain and rash) or improved (ie, significant pain relief and rash subsistence). Rates of therapeutic efficacy were 97.2% in the HBOT group and 81.3% in the medication group. The difference between groups was statistically significant ( $p < 0.05$ ). In the HBOT 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 included 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 HBOT on health outcomes for patients with herpes zoster.

### *Fibromyalgia*

One quasi-randomized trial and 1 delayed-treatment RCT on HBOT for fibromyalgia were identified. In 2004, a study by Yildiz et al included 50 patients with fibromyalgia who had ongoing symptoms despite medical and physical therapy. On an alternating basis, patients were assigned to HBOT or a control group. HBOT consisted of fifteen 90-minute sessions at 2.4 ata (1 session per day, 5 d/wk). The control group breathed room air at 1 ata on the same schedule. Baseline values on the 3 outcomes were similar in the 2 groups. After the course of HBOT treatment, the mean (SD) number of tender points were 6.04 (1.18) in the HBOT group and 12.54 (1.10) in the control group. The mean (SD) pain threshold was 1.33 kg (0.12) and 0.84 kg (0.12), respectively, and the mean VAS was 31.54 (8.34) and 55.42 (6.58), respectively. In the study abstract, the authors stated that there were statistically significant differences between the HBOT and the control groups after 15 therapy sessions, but the table presenting outcomes lacked the notation used to indicate between-group statistical significance. It is not clear whether the control group actually received a sham intervention that would minimize any placebo effect (ie, whether the control intervention was delivered in a hyperbaric chamber). The authors stated that the study was double-blind but did not specify any details of patient blinding.

In 2015, Efrati et al published an RCT that included 60 female patients who had fibromyalgia for at least 2 years and were symptomatic. Patients were randomized to an immediate 2-month course of HBOT or delayed HBOT after 2 months. The HBOT protocol was forty 90-minute sessions of 100% oxygen at 2 ata (1 session per day, 5 d/wk). Forty-eight of 60 patients (80%) completed the study and were included in the analysis. After the initial 2 months, outcomes including number of tender points, pain threshold, and QOL (SF-36) were significantly better in the immediate treatment group than the delayed treatment group (which received no specific intervention during this time). After the delayed treatment group had undergone HBOT, outcomes were significantly improved compared with scores prior to HBOT treatment. These findings are

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consistent with a clinical benefit of HBOT, but also with a placebo effect. A sham-control is needed to confirm the efficacy of HBOT in the treatment of fibromyalgia and other conditions where primary end points are pain and other subjective outcomes.

The above studies were few in number with relatively small sample sizes and they have methodological limitations (eg, quasi-randomization and no or uncertain sham control for a condition with subjective outcomes susceptible to a placebo effect). Moreover, the HBOT protocol varied (eg, 15 HBOT sessions vs 40 HBOT sessions). Thus, the evidence is insufficient to draw conclusions about the impact of HBOT on health outcomes for patients with fibromyalgia.

### *Mental Illness*

A Rapid Response Report from the Canadian Agency for Drugs and Technologies in Health searched the literature through July 2014 on the clinical effectiveness of HBOT for treatment of adults with posttraumatic stress disorder, generalized anxiety disorder, and/or depression. The review's inclusion criteria were health technology assessments, systematic reviews, meta-analyses, RCTs, or nonrandomized studies comparing HBOT with any active treatment and reporting clinical outcomes. No eligible studies were identified.

### *Multiple Sclerosis*

A Cochrane review of RCTs on HBOT for multiple sclerosis was published by Bennett et al in 2004. The authors identified 9 RCTs, with a total of 504 participants, that compared the effects of HBOT with placebo or no treatment. The primary outcome of the review was score on the Expanded Disability Status Scale (EDSS). A pooled analysis of data from 5 trials (n=271) did not find a significant difference in change in the mean EDSS after 20 HBOT treatments versus control (mean difference [MD], -0.07; 95% CI, -0.23 to 0.09). Moreover, a pooled analysis of data from 3 trials (n=163) comparing HBOT and placebo did not find a significant difference in mean EDSS after 6 months of follow-up (MD = -0.22; 95% CI, -0.54 to 0.09).

### *Other indications*

For the indications listed below, insufficient evidence to support the use of HBOT was identified. Since 2000, there have been no published controlled trials or large case series (ie,  $\geq 25$  patients):

- Bone grafts;
- Carbon tetrachloride poisoning, acute;
- Cerebrovascular disease, acute (thrombotic or embolic) or chronic;
- Fracture healing;
- Hydrogen sulfide poisoning;
- Intra-abdominal and intracranial abscesses;
- Lepromatous leprosy;
- Meningitis;
- Pseudomembranous colitis (antimicrobial agent-induced colitis);
- Radiation myelitis;
- Sickle cell crisis and/or hematuria;
- Amyotrophic lateral sclerosis;

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- Retinal artery insufficiency, acute;
- Retinopathy, adjunct to scleral buckling procedures in patients with sickle cell peripheral retinopathy and retinal detachment;
- Pyoderma gangrenosum;
- Tumor sensitization for cancer treatments, including but not limited to, radiotherapy or chemotherapy;

### Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in June 2015 did not identify any ongoing or unpublished trials that would likely influence this review.

### Summary of Evidence

The evidence for the use of topical HBOT in individuals who might respond to increased oxygen delivery to tissues includes primarily of case series and case reports. Relevant outcomes are overall survival, symptoms, change in disease status, and functional outcomes. Only 1 RCT was published on any indication. This study, in patients with diabetic foot ulcers, had a small sample size and did not find a significant benefit of topical hyperbaric oxygen therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for the use of systemic HBOT in individuals with nonhealing diabetic wounds of the lower extremities, acute traumatic ischemia, soft-tissue radiation necrosis (eg, radiation enteritis, cystitis, proctitis), osteoradionecrosis (ie, pre- and posttreatment), planned dental surgery (non-implant-related) of an irradiated jaw, gas gangrene, and profound anemia with exceptional blood loss when blood transfusion is impossible or must be delayed includes systematic reviews and/or recommendations from the Undersea and Hyperbaric Medical Society's (UHMS). Relevant outcomes include overall survival, symptoms, change in disease status, and functional outcomes. For all of the above indications, evidence and/or USMS guidelines support use of HBOT. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in health outcomes.

The evidence for the use of systemic HBOT in individuals with any condition other than those specified in the previous paragraph includes systematic reviews, 1 or a few small RCTs or small uncontrolled studies. Relevant outcomes include overall survival, symptoms, change in disease status, and functional outcomes. The available studies do not demonstrate that HBOT improves relevant outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Clinical Input Received From Physician Specialty Societies and Academic Medical Centers

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

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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. The clinical input varied depending on the condition. There was universal agreement that topical HBOT and systemic HBOT for autism spectrum disorder 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 HBOT. Several reviewers acknowledged that there is a paucity of clinical trials on HBOT for compromised skin grafts/flaps, necrotizing soft tissue infections, and chronic refractory osteomyelitis. These reviewers commented on the support from basic science, animal studies, and retrospective case series, as well as lack of effective alternative treatments for these conditions. Based on the available evidence and clinical input, acute carbon monoxide poisoning and chronic refractory osteomyelitis were changed in 2010 to medically necessary indications for HBOT. However, despite the clinical input and given the limited published evidence, compromised skin grafts and flaps and necrotizing soft tissue infections are still considered investigational.

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| 08/19/2003 | Medical Policy Committee review   |
| 08/25/2003 | Managed Care Advisory Council approval  |
| 08/10/2004 | Medical Director review   |
| 08/17/2004 | Medical Policy Committee review   |
| 08/31/2004 | Medical Director review   |
| 09/21/2004 | Medical Policy Committee review. Format revision and the following changes to coverage eligibility: Retinal artery insufficiency deleted from list of covered conditions. Prophylactic pre- and post-treatment for patients undergoing dental surgery of a radiated jaw added to the list of covered conditions.  |
| 09/27/2004 | Managed Care Advisory Council approval  |
| 10/10/2005 | Medical Director review   |
| 10/18/2005 | Medical Policy Committee review. Format revision. Clinical criteria revision. HBO2 for acute coronary syndromes and as an adjunct to percutaneous coronary interventions added to investigational indications. Coverage eligibility changes. Refractory mycoses, mucormycosis, actinomycosis and canidiobolus coronato changed from eligible for coverage to investigational. <i>Effective date of policy will reflect 60 day period following the notification of providers that coverage eligibility has changed.</i> |
| 10/27/2005 | Managed Care Advisory Council approval  |
| 01/10/2007 | Medical Director review   |
| 01/17/2007 | Medical Policy Committee approval. Format revision. Coverage eligibility unchanged.   |
| 12/05/2007 | Medical Director review   |

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12/19/2007	Medical Policy Committee approval. Coverage eligibility unchanged. Added autism as investigational.
12/03/2008	Medical Director review
12/17/2008	Medical Policy Committee approval. No change to coverage.
07/02/2009	Medical Director review
07/22/2009	Medical Policy Committee approval. No change to coverage eligibility.
07/01/2010	Medical Policy Committee approval
07/21/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/07/2011	Medical Policy Committee review
07/20/2011	Medical Policy Implementation Committee approval. Changed chronic refractory osteomyelitis from investigational to eligible for coverage.
06/28/2012	Medical Policy Committee review
07/27/2012	Medical Policy Implementation Committee approval. Acute surgical and traumatic wounds, idiopathic femoral neck necrosis, chronic arm lymphedema following radiotherapy for cancer, radiation-induced injury in the head and neck added as investigational. Changed chronic diabetic wounds to chronic non-diabetic wounds as an investigational indication, since chronic diabetic wounds are covered.
08/01/2013	Medical Policy Committee review
08/21/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/07/2014	Medical Policy Committee review
08/20/2014	Medical Policy Implementation Committee approval. Added vascular dementia, herpes zoster, motor dysfunction associated with stroke, and bisphosphonate-related osteonecrosis of the jaw as investigational.
10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. Clarified soft tissue radiation necrosis. Radiation myelitis, cystitis, enteritis or proctitis was removed from investigational section.
01/01/2015	Coding Update
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
12/03/2015	Medical Policy Committee review
12/16/2015	Medical Policy Implementation Committee approval. Indications added to INV statement: Fibromyalgia, mental illness (ie, posttraumatic stress disorder, generalized anxiety disorder or depression), and Inflammatory bowel disease (Crohn disease or ulcerative colitis).
12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date:	12/2018

### **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2016 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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# Louisiana

## Hyperbaric Oxygen Pressurization (HBO)

Policy # 00070  
 Original Effective Date: 08/25/2003  
 Current Effective Date: 12/20/2017

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*CPT is a registered trademark of the American Medical Association.*

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	99183
HCPCS	A4575, G0277
ICD-10 Diagnosis	A18.01                      A18.03                      A42.0-A42.2                      A42.81-A42.89
	A42.9-A42.39                      A48.0                      A50.01-A50.09                      A56.01
	B02.0-B02.1                      B02.21-B02.39                      B02.7-B02.9                      B36.0-B36.9
	B37.0-B37.3                      B37.41-B37.49                      B37.5-B37.7                      B37.81-B37.89
	B47.1-B47.9                      B48.3                      B48.8                      B49
	B78.1                      D62                      E08.52                      E08.628
	E09.52                      E09.628                      E10.52                      E11.52
	E13.52                      E83.2                      F01.50-F01.51                      F32.0-F32.5
	F32.89                      F32.9-F33.3                      F33.40-F33.42                      F33.9
	F34.81-F34.89                      F41.0-F41.9                      F43.10-F43.12                      G93.6
	H05.021-H05.029                      I69.031-I69.069                      I69.131-I69.169                      I69.231-I69.269
	I69.331-I69.369                      I69.831-I69.869                      I69.931-I69.969                      I70.231-I70.249
	I70.331-I70.369                      I70.431-I70.469                      I70.531-I70.569                      I70.631-I70.669
	I70.731-I70.769                      I73.01                      I73.9                      I87.9
	I96                      I99.9                      K12.2                      K50.00
	K50.011-K50.019                      K50.10-K50.119                      K50.80-K50.819                      K50.90-K50.919
	K51.0-K51.019                      K51.20-K51.219                      K51.30-K51.319                      K51.40-K51.419
	K51.50-K51.519                      K51.80-K51.819                      K51.90-K51.919                      K52.0

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L02.01	L02.11-L02.219	L02.31	L02.411-L02.419
L02.511-L02.519	L02.611-L02.619	L02.811-L02.818	L02.91
L03.115-L03.129	L03.211-L03.91	L08.0-L08.9	L44.8-L44.9
L45	L59.9	L88	L92.8
L94.2	L94.4	L97.101-L97.129	L97.201-L97.229
L97.301-L97.329	L97.401-L97.429	L97.501-L97.529	L97.801-L97.829
L97.901-L97.929	L98.0-L98.8	L99	M27.2-M27.8
M46.20-M46.28	M60.80-M60.879	M60.88-M60.89	M60.9
M79.1	M79.7	M86.00-M86.079	M86.08-M86.09
M86.10-M86.179	M86.18-M86.19	M86.20-M86.279	M86.28-M86.29
M86.30-M86.379	M86.38-M86.39	M86.40-M86.479	M86.48-M86.49
M86.50-M86.579	M86.58-M86.59	M86.60-M86.679	M86.68-M86.69
M86.8X0-M86.8X9	M86.9	M87.08	M87.180
M90.80-M90.879	M90.88-M90.89	N30.00-N30.01	N30.10-N30.91
P10.0-P10.19	P11.0-P11.9	P52.4	P52.6-P52.9
S06.1X0A-S06.1X9A	S07.0XXA	S07.1XXA	S07.8XXA
S07.9XXA	S17.0XXA	S17.8XXA	S17.9XXA
S28.0XXA	S38.001A	S38.002A	S38.01XA
S38.02XA	S38.03XA	S38.1XXA	S47.1XXA
S47.2XXA	S47.9XXA	S57.00XA	S57.01XA
S57.02XA	S57.80XA	S57.81XA	S57.82XA
S67.00XA	S67.01XA	S67.02XA	S67.10XA
S67.190A	S67.191A	S67.192A	S67.193A
S67.194A	S67.195A	S67.196A	S67.197A
S67.198A	S67.20XA	S67.21XA	S67.22XA
S67.30XA	S67.31XA	S67.32XA	S67.40XA
S67.41XA	S67.42XA	S67.90XA	S67.91XA
S67.92XA	S77.00XA	S77.00XA	S77.01XA
S77.02XA	S77.10XA	S77.11XA	S77.12XA
S77.20XA	S77.21XA	S77.22XA	S87.00XA
S87.01XA	S87.02XA	S87.80XA	S87.81XA

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S87.82XA	S97.00XA	S97.01XA	S97.02XA
S97.101A	S97.102A	S97.109A	S97.111A
S97.112A	S97.119A	S97.121A	S97.122A
S97.129A	S97.80XA	S97.81XA	S97.82XA
T31.0-T31.99	T32.0-T32.99	T58.01XA	T58.02XA
T58.03XA	T58.04XA	T58.11XA	T58.12XA
T58.13XA	T58.14XA	T58.2X1A	T58.2X2A
T58.2X3A	T58.2X4A	T58.8X1A	T58.8X2A
T58.8X3A	T58.8X4A	T58.91XA	T58.92XA
T58.93XA	T58.94XA	T63.001A	T63.002A
T63.003A-T63.004A	T63.011A-T63.014A	T63.021A-T63.024A	T63.031A-T63.034A
T63.041A-T63.044A	T63.061A-T63.064A	T63.071A-T63.074A	T63.081A-T63.084A
T63.091A-T63.094A	T63.111A-T63.114A	T63.121A-T63.124A	T63.191A-T63.194A
T63.2X1A-T63.2X4A	T63.301A-T63.304A	T63.311A-T63.314A	T63.321A-T63.324A
T63.331A-T63.334A	T63.391A-T63.394A	T63.411A-T63.414A	T63.421A-T63.424A
T63.431A-T63.434A	T63.441A-T63.444A	T63.451A-T63.454A	T63.461A-T63.464A
T63.481A-T63.484A	T63.511A-T63.514A	T63.591A-T63.594A	T63.611A-T63.614A
T63.621A-T63.624A	T63.631A-T63.634A	T63.691A-T63.694A	T63.711A-T63.714A
T63.791A-T63.794A	T63.811A-T63.814A	T63.821A-T63.824A	T63.831A-T63.834A
T63.891A-T63.894A	T63.91XA-T63.94XA	T65.0X1A-T65.0X4A	T66.XXXA
T70.3XXA	T70.90XXA	T8572XA	T85.79XA
T86.820-T86.829	T86.842-T86.849		

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with the Blue Cross and Blue Shield Association TEC or other nonaffiliated technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

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### 3. Reference to federal regulations.

**\*\*Medically Necessary (or "Medical Necessity")** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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