Hyperbaric Oxygen Pressurization (HBO)

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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 Are 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 in the treatment of the following conditions to be **eligible for coverage.****

- Non healing diabetic wounds of the lower extremities in patients who meet ALL of the following criteria:
    - Patient has type 1 or type 2 diabetes and has a lower-extremity wound due to diabetes; and
    - Patient has a wound classified as Wagner grade 3 or higher (see Policy Guidelines section); and
    - Patient has no measurable signs of healing after 30 days of an adequate course of standard wound therapy (see Policy Guidelines section); and
    - Standard wound therapy will be continued; and
    - Wounds will be evaluated at least every 30 days and hyperbaric oxygen pressurization (HBO) continued only if measurable signs of healing have been documented within 30-day period of treatment;
- Acute traumatic peripheral ischemia (eg, crush injuries, suturing of severed limbs, reperfusion injury, compartment syndrome);
- Acute peripheral arterial insufficiency;
- Decompression sickness;
- Gas embolism, acute;
- Gas gangrene (ie, clostridial myonecrosis);
- Progressive necrotizing soft tissue infections (necrotizing fasciitis);

- Preparation and preservation of compromised skin grafts (not for primary management of wounds),
- Cyanide poisoning, acute;
- Acute carbon monoxide poisoning;
- Soft-tissue radiation necrosis (eg, radiation enteritis, cystitis, proctitis) and osteoradionecrosis;
- Pre- and post-treatment for patients undergoing dental surgery (non-implant-related) of an irradiated jaw;
- Profound anemia with exceptional blood loss: only when blood transfusion is impossible or must be delayed; and
- Acute and chronic treatment-refractory osteomyelitis.
- Central retinal artery occlusion when treatment is initiated within 24 hours after initial vision loss.

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 therapy to be **investigational.***

Based on review of available data, the Company considers limb specific hyperbaric oxygen therapy to be **investigational.***

Based on review of available data, the Company considers hyperbaric oxygen pressurization in all other situations, including but not limited to, the treatment of the following conditions to be **investigational:***

- Bisphosphonate-related osteonecrosis of the jaw;
- Acute thermal burns;
- Acute surgical and traumatic wounds;
- Chronic wounds, other than those in patients with diabetes who meet the criteria specified in the medically necessary statement;

- Spinal cord injury;
- Traumatic brain injury;
- Inflammatory bowel disease (Crohn disease or ulcerative colitis);
- Brown recluse spider bites;
- 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;
- Demyelinating diseases (eg, multiple sclerosis, amyotrophic lateral sclerosis);
- Retinal artery insufficiency, acute;
- Retinopathy, adjunct to scleral buckling procedures in patients with sickle cell peripheral retinopathy and retinal detachment;
- Pyoderma gangrenosum;
- Acute coronary syndromes and as an adjunct to coronary interventions, including but not limited to, percutaneous coronary interventions and cardiopulmonary bypass;
- Idiopathic sudden sensorineural hearing loss;
- Refractory mycoses: mucormycosis, actinomycosis, conidiobolus coronato;
- Cerebral edema, acute;
- Migraine;
- In vitro fertilization;
- Cerebral palsy;
- Tumor sensitization for cancer treatments, including but not limited to, radiotherapy or chemotherapy;
- Delayed-onset muscle soreness;
- Idiopathic femoral neck necrosis;

- Chronic arm lymphedema following radiotherapy for cancer;
- Early treatment (beginning at completion of radiotherapy) to reduce adverse events of radiotherapy;
- Autism spectrum disorder;
- Bell palsy;
- Acute ischemic stroke;
- Motor dysfunction associated with stroke;
- Herpes zoster;
- Vascular dementia;
- Fibromyalgia; and
- Mental illness (ie, posttraumatic stress disorder, generalized anxiety disorder or depression).

Policy Guidelines

Topical Hyperbaric Oxygen

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

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

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

Systemic Hyperbaric Oxygen

The Wagner classification system categorizes wounds 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.

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

- 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
- Severe anemia

- Intracranial abscess
- Necrotizing soft tissue infections
- Osteomyelitis (refractory)
- Delayed radiation injury (soft tissue and bony necrosis)
- Compromised grafts and flaps
- Acute thermal burn injury
- Idiopathic sudden sensorineural hearing loss.

Background/Overview

Hyperbaric Oxygen Therapy

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

Systemic HBOT

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

Topical HBOT

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

Adverse Events
HBOT is a generally safe therapy, with an estimated adverse side effect rate of 0.4%. Adverse events may occur either from pressure effects or the oxygen. The pressure effect (barotrauma) may affect any closed air-filled cavity such as ears, sinus, teeth, and lungs. Pain and/or swelling may occur at these sites as pressure increases during the procedure, and decreases as the procedure is ending. Oxygen toxicity may affect the pulmonary, neurologic, or ophthalmologic systems. Pulmonary symptoms include a mild cough, substernal burning, and dyspnea. Neurologic effects include tunnel vision, tinnitus, nausea, and dizziness. Ophthalmologic effects include retinopathy in neonates, cataract formation, and transient myopic vision changes.

Note that this evidence review does not address topical oxygen therapy in the absence of pressurization.

FDA or Other Governmental Regulatory Approval

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

Rationale/Source

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

For individuals with wounds, burns or infections who receive topical HBOT, the evidence includes a systematic review, case series, and a randomized controlled trial (RCT). Relevant outcomes are overall survival, symptoms, change in disease status, and functional outcomes. The systematic review identified 3 RCTs including patients with sacral pressure ulcers, ischial pressure ulcers, and refractory venous ulcers. All trials reported that healing improved significantly after HBOT than

after standard of care. Pooling of results was not possible due to heterogeneity in patient populations and treatment regimens. The single small RCT (N=28) was not included in the review and the uncontrolled studies do not provide sufficient data that topical HBOT is efficacious. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with chronic diabetic ulcers who receive systemic HBOT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms and change in disease status. Meta-analyses of RCTs found significantly higher diabetic ulcer healing rates with HBOT than with control conditions. One of the 2 meta-analyses found that HBOT was associated with a significantly lower rate of major amputation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

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

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

For individuals with chronic refractory osteomyelitis who receive systemic HBOT, the evidence includes case series. Relevant outcomes are symptoms and change in disease status. The case series reported high rates of successful outcomes (no drainage, pain, tenderness, or cellulitis) in patients with chronic refractory osteomyelitis treated with HBOT. However, controlled studies are needed to

determine conclusively the impact of HBOT on health outcomes compared with other interventions. The evidence is insufficient to determine the effects of the technology on health outcomes.

However, clinical input obtained in 2010 and Undersea and Hyperbaric Medical Society guidelines support HBOT for the treatment of chronic refractory osteomyelitis. Thus, based on clinical input and guideline support, this indication may be considered medically necessary.

For individuals with acute thermal burns who receive systemic HBOT, the evidence includes a systematic review of 2 RCTs. Relevant outcomes are overall survival, symptoms, and change in disease status. Only 2 RCTs were identified, and both were judged to have poor methodologic quality. Evidence from well-conducted controlled trials is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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

For individuals with necrotizing soft tissue infections who receive systemic HBOT, the evidence includes systematic reviews and a retrospective cohort study. Relevant outcomes are overall survival, symptoms, and change in disease status. A Cochrane review did not identify any RCTs. Another systematic review identified a retrospective cohort study, which did not find better outcomes after HBOT than after standard care without HBOT in patients with necrotizing soft tissue

infections. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with acute coronary syndrome who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are overall survival, symptoms, change in disease status, and functional outcomes. A Cochrane review identified 6 RCTs. There were 2 pooled analyses, one found significantly lower rates of death with HBOT and the other reported inconsistent results in left ventricular function. Additional RCT data are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals with motor dysfunction associated with stroke who receive systemic HBOT, the evidence includes an RCT. Relevant outcomes are symptoms and functional outcomes. The RCT, which used a crossover design, found better outcomes with HBOT at 2 months than with delayed treatment. However, the trial had a number of methodologic limitations (eg, lack of patient blinding, heterogeneous population, high dropout rate) that make it difficult to evaluate the efficacy of HBOT. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals with traumatic brain injury who receive systemic HBOT, the evidence includes RCTs and systematic reviews. Relevant outcomes are overall survival, symptoms, change in disease status, and functional outcomes. RCTs were heterogenous regarding intervention protocols, patient populations, and outcomes reported. Systematic reviews conducted pooled analyses only on a

minority of the published RCTs, and these findings were inconsistent. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with inflammatory bowel disease who receive systemic HBOT, the evidence includes an RCT, observational studies, and a systematic review. Relevant outcomes are symptoms, change in disease status and functional outcomes. One small RCT has been published, and this trial did not find a significant improvement in health outcomes when HBOT was added to standard medical therapy. A systematic review including the RCT and observational studies found a high rate of bias in the literature due to attrition and reporting bias. The evidence is insufficient to determine the effects of the technology on health outcomes.

A Cochrane review of RCTs had mixed findings from studies that included individuals with tinnitus. Some outcomes (ie, improvement in hearing of all frequencies, >25% return of hearing) were better with HBOT than with a control intervention, but more than 50% return of hearing did not differ significantly between groups. There was important variability in the patients enrolled in the studies. A subsequent systematic review had similarly limited conclusions due to the inclusion of non-randomized studies. One RCT included in this review included patients with ISSNHL and found no differences in HBOT treatment compared with steroid injections in mean hearing thresholds at 0.25, 0.5, 1, and 4 kHz; however, a significant difference was detected at the 2-kHz level. Nonrandomized studies of HBOT used as adjunctive therapy did not support incremental value. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals with autism spectrum disorder who receive systemic HBOT, the evidence includes an RCT and a systematic review. Relevant outcomes are symptoms and functional outcomes. A Cochrane review identified a single RCT on HBOT for autism spectrum disorder and this trial did not find significantly better parental-assessed or clinician-assessed outcomes with HBOT compared with sham. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with cerebral palsy who receive systemic HBOT, the evidence includes 2 RCTs and an observational study. Relevant outcomes are symptoms and functional outcomes. One RCT was stopped early due to futility, and the other did not find significantly better outcomes with HBOT than with a sham intervention. The observational study focused on sleep disorders in children with cerebral palsy and reported improvements with the HBOT treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with vascular dementia who receive systemic HBOT, the evidence includes an RCT and a systematic review. Relevant outcomes are symptoms and functional outcomes. The Cochrane review identified only a single RCT with methodologic limitations. Well-conducted controlled trials are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with radiotherapy adverse events who receive systemic HBOT, the evidence includes RCTs, nonrandomized comparator trials, case series, and systematic reviews. Relevant outcomes are symptoms and functional outcomes. Two systematic reviews were identified, but pooled analyses were not possible due to heterogeneity in treatment regimens and outcomes measured. One systematic review concluded that more RCTs would be needed. The 2 RCTs identified had inconsistent findings. One reported no short-term benefit with HBOT, but some benefits 12 months after radiotherapy; the other did not find a significant benefit of HBOT at 12-month follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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

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

For individuals with fibromyalgia who receive systemic HBOT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Only 2 RCTs were identified, and both reported positive effects of HBOT on tender points and pain. However, the trials had relatively small samples and methodologic limitations (eg, quasi-randomization, no or uncertain sham control for a condition with subjective outcomes susceptible to a placebo effect). Moreover, the HBOT protocols varied. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with multiple sclerosis who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms and functional outcomes. A Cochrane review of RCTs did not find a significant difference in Expanded Disability Status Scale scores when patients with multiple sclerosis were treated with HBOT vs a comparator intervention. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers,

input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 6 physician specialty societies and 5 academic medical centers while this policy was under review in 2010. Clinical input varied by condition. There was consensus that topical hyperbaric oxygen therapy (HBOT) and systemic HBOT for autism spectrum disorder and headache/migraine are investigational. There was also wide support for adding acute carbon monoxide poisoning, compromised skin grafts or flaps, chronic refractory osteomyelitis, and necrotizing soft tissue infections to the list of medically necessary indications for HBOT. Several reviewers acknowledged that there is a paucity of clinical trials on HBOT for compromised skin grafts/flaps, necrotizing soft tissue infections, and chronic refractory osteomyelitis. These reviewers commented on the support from basic science, animal studies, and retrospective case series, as well as lack of effective alternative treatments for these conditions. Based on the available evidence and clinical input, acute carbon monoxide poisoning and chronic refractory osteomyelitis were changed in 2010 to medically necessary indications for HBOT. However, despite the clinical input and given the limited published evidence, compromised skin grafts and flaps and necrotizing soft tissue infections are still considered investigational.

Practice Guidelines and Position Statements

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

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

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

Society of Vascular Surgery et al
In 2016, the Society of Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine published guidelines on the management of the diabetic foot. According to the guidelines, for diabetic foot ulcers that fail to demonstrate improvement (>50% wound area reduction) after a minimum of 4 weeks of standard wound therapy, adjunctive therapy such as HBOT is recommended (grade 1B). Also, for diabetic foot ulcers with adequate perfusion that fail to respond to 4 to 6 weeks of conservative management, HBOT is suggested (grade 2B).

Other Conditions

Undersea and Hyperbaric Medical Society
The 2014 UHMS hyperbaric oxygen therapy indications committee report included the following indications as recommended:
1. Air or Gas Embolism
2. Carbon Monoxide Poisoning and carbon monoxide complicated by cyanide poisoning
3. Clostridial Myositis and Myonecrosis (Gas Gangrene)
4. Crush Injury, Compartment Syndrome and Other Acute Traumatic Ischemias
5. Decompression Sickness
6. Arterial Insufficiencies
7. Severe Anemia
8. Intracranial Abscess
9. Necrotizing Soft Tissue Infections
10. Osteomyelitis (Refractory)
11. Delayed Radiation Injury (Soft Tissue and Bony Necrosis)
12. Compromised Grafts and Flaps
13. Acute Thermal Burn Injury
14. Idiopathic Sudden Sensorineural Hearing Loss.

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

American Academy of Otolaryngology-Head and Neck Surgery
In 2012, the American Academy of Otolaryngology-Head and Neck Surgery published clinical guidelines on treatment of sudden hearing loss. The guidelines included a statement that HBOT may be considered a treatment option for patients who present within 3 months of a diagnosis of idiopathic sudden sensorineural hearing loss (ISSNHL): "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 ISSNHL" (grade B recommendation, based on systematic review of RCTs with methodological limitations).

Tenth European Consensus Conference on Hyperbaric Medicine
The 10th European Consensus Conference on Hyperbaric Medicine (ECHM) convened in April 2016 to update HBOT indication recommendations. Evidence was assessed using a modified GRADE system with the DELPHI system for consensus evaluation. Table 1 presents the updated recommendations:

Table 1. Recommendations on Hyperbaric Medicine

Condition	SOR	LOE
Carbon monoxide poisoning	Strong	Moderate
Open fractures with crush injury	Strong	Moderate
Prevention of osteoradionecrosis	Strong	Moderate

Osteoradionecrosis (mandible)	Strong	Moderate
Soft tissue radionecrosis (cystitis, proctitis)	Strong	Moderate
Decompression illness	Strong	Low
Gas embolism	Strong	Low
Anaerobic or mixed bacterial infection	Strong	Low
Sudden deafness	Strong	Moderate
Diabetic foot lesions	Weak	Moderate
Femoral head necrosis	Weak	Moderate
Compromised skin grafts and musculocutaneous flaps	Weak	Low
Central retinal artery occlusion	Weak	Low
Crush injury without fracture	Weak	Low
Osteoradionecrosis (other than mandible)	Weak	Low

Radio-induced lesions of soft tissues	Weak	Low
Radio-induced lesions of soft tissues (preventive)	Weak	Low
Ischemic ulcers	Weak	Low
Refractory chronic osteomyelitis	Weak	Low
Burns, second degree, >20% body surface area	Weak	Low
Pneumatosis cystoides intestinalis	Weak	Low
Neuroblastoma, stage IV	Weak	Low
Brain injury in highly selected patients	Neutral	Low
Radio-induced lesions of larynx	Neutral	Low
Radio-induced lesions of central nervous system	Neutral	Low
Post-vascular procedure reperfusion syndrome	Neutral	Low
Limb replantation	Neutral	Low

Selected non-healing wounds, secondary to systemic process	Neutral	Low
Sickle cell disease	Neutral	Low
Interstitial cystitis	Neutral	Low

Adapted from Mathieu et al (2017).
LOE: level of evidence; SOR: strength of recommendation.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
In 2003, the Centers for Medicare & Medicaid added Medicare coverage of HBOT for diabetic wounds of the lower extremities meeting certain criteria. As of the current coverage statement, Medicare coverage is provided for HBOT administered in a chamber for the following conditions:

1. "Acute carbon monoxide intoxication,
2. Decompression illness,
3. Gas embolism,
4. Gas gangrene,
5. 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.
6. 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.
7. Progressive necrotizing infections (necrotizing fasciitis),
8. Acute peripheral arterial insufficiency,
9. Preparation and preservation of compromised skin grafts (not for primary management of wounds),
10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management,

11. Osteoradionecrosis as an adjunct to conventional treatment,
12. Soft tissue radionecrosis as an adjunct to conventional treatment,
13. Cyanide poisoning,
14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment,
15. Diabetic wounds of the lower extremities in patients who meet the following three criteria:
    a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
    b. Patient has a wound classified as Wagner grade III or higher; and
    c. 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, débridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment."

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01659723	Radiation Induced Cystitis Treated With Hyperbaric Oxygen - A Randomized Controlled Trial (RICH-ART)	80	Aug 2018
NCT03147352	Pro-Treat - Prognosis and Treatment of Necrotizing Soft Tissue Infections: a Prospective Cohort Study	310	Jan 2018
NCT02089594	Hyperbaric Oxygen Therapy Treatment of Chronic Mild Traumatic Brain Injury (mTBI)/Persistent Post-Concussion Syndrome (PCCS)	59	Mar 2019
NCT02714465	Treatment of Adverse Radiation Effects after Gamma Knife Radiosurgery (GKS) by Hyperbaric Oxygen Therapy (HBO)	65	May 2019
NCT03325959	Hyperbaric Oxygen versus Standard Pharmaceutical Therapies for Fibromyalgia Syndrome - Prospective, Randomized, Crossover Clinical Trial	70	Nov 2019

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT00596180	Hyperbaric Oxygen Therapy and SPECT Brain Imaging in Carbon Monoxide Poisoning	40	Dec 2019
NCT01002209	Postoperative Hyperbaric Oxygen Treatments to Reduce Complications in Diabetic Patients Undergoing Vascular Surgery (HODiVA)	112	Oct 2020
NCT01847755	Phase 1-2 Study of Hyperbaric Treatment of Traumatic Brain Injury	100	Dec 2020
Unpublished			
NCT02085330	Hyperbaric Oxygen Therapy for Mild Cognitive Impairment	60	Feb 2017 (unknown)

NCT: national clinical trial.

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Policy History

Original Effective Date: 08/25/2003
Current Effective Date: 05/11/2020

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, mucomycosis, actinomycosis and canidiobolus coronato changed from eligible for coverage to investigational. *Effective date of policy will reflect 60 day period following the notification of providers that coverage eligibility has changed*.
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
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.
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. No change to coverage.

Hyperbaric Oxygen Pressurization (HBO)

Policy # 00070
Original Effective Date: 08/25/2003
Current Effective Date: 05/11/2020

01/01/2019	Coding update
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Added coverage for central retinal artery occlusion when treatment is initiated within 24 hours after initial vision loss and acute gas embolism. Brown recluse spider bites changed to investigational. Coding update.
04/02/2020	Medical Policy Committee review
04/08/2020	Medical Policy Implementation Committee approval. Removed radiation-induced injury in the head and neck, except as noted earlier in the medically necessary statement from the investigational section.
09/10/2020	Coding update

Next Scheduled Review Date: 04/2021

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 2019 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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Hyperbaric Oxygen Pressurization (HBO)

Policy # 00070
Original Effective Date: 08/25/2003
Current Effective Date: 05/11/2020

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-A42.39, A48.0, A50.01-A50.09, A56.01, B02.0-B02.9, B36.0-B36.9, B37.0-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-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, 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, M79.11-M79.18, 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, 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, T58.13XA, 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, Delete codes eff 10/1/2020: T86.842-T86.849 Added codes eff 10/1/2020: T86.8401-T86.8409, T86.8411-T86.8419, T86.8421-T86.8429, T86.8481-T86.8489, T86.8491-T86.8499

*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. Food and Drug Administration (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 technology assessment program (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
    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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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.