LOUISIANA BLUE

Hyperbaric Oxygen Therapy (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 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 therapy (HBO) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility may be considered for systemic hyperbaric oxygen therapy (HBO) in the treatment of **ANY** of the following conditions:

- 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 HBO continued only if measurable signs of healing have been documented within 30-day period of treatment; **OR**
- Acute traumatic peripheral ischemia (eg, crush injuries, suturing of severed limbs, reperfusion injury, compartment syndrome); **OR**
- Peripheral arterial insufficiency related to non-healing arterial insufficiency ulcers with no measurable signs of healing after 30 days of an adequate course of standard wound therapy; **OR**
- Decompression sickness; **OR**
- Gas embolism, acute; **OR**
- Gas gangrene (ie, clostridial myonecrosis); **OR**

- Progressive necrotizing soft tissue infections (necrotizing fasciitis, see Policy Guidelines); **OR**
- Compromised skin grafts or flaps (not for primary management of wounds) with any of the following (see Policy Guidelines):
    - visible ischemic changes such as pallor, mottling, or frank necrosis of the overlying skin; **OR**
    - documented hypoxia or decreased perfusion and transcutaneous oxygen tension TcPO2 less than 40 mm Hg on room air; **OR**
- Cyanide poisoning, acute; **OR**
- Acute carbon monoxide poisoning; **OR**
- Soft-tissue radiation necrosis (eg, radiation enteritis, cystitis, proctitis) and osteoradionecrosis; **OR**
- Pre- and post-treatment for patients undergoing dental surgery (non-implant-related) of an irradiated jaw; **OR**
- Profound anemia with exceptional blood loss: only when blood transfusion is impossible or must be delayed; **OR**
- Acute and chronic treatment-refractory osteomyelitis (see Policy Guidelines); **OR**
- Idiopathic sudden sensorineural hearing loss (ISSHL) in individuals with a loss of 30 decibels or more or hearing loss at least 61 decibels of pure tone thresholds when HBOT is combined with steroid therapy (systemic or intra-tympanic) and initiated within 1 month of onset of SSNHL; **OR**
- Central retinal artery occlusion (CRAO).

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 (HBOT) to be **investigational.***

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

Based on review of available data, the Company considers systemic hyperbaric oxygen therapy (HBO) 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 peripheral artery insufficiency (outside of other listed medically necessary indications involving arterial insufficiency) (see Policy Guidelines);
- Acute thermal burns;
- Acute surgical and traumatic wounds not meeting criteria specified in the eligible for coverage statement;

- Chronic wounds, other than those in patients with diabetes who meet the criteria specified in the eligible for coverage 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);
- 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;
- 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

Evidence

There is limited comparative evidence for HBOT. The policy is based on the best available evidence, and is largely informed by clinical input and 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 HBOT 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.

HBOT refers to treatment at pressures greater than 1.4 atmospheres absolute, administered in a hard-sided hyperbaric chamber that meets applicable safety standards. Tissue oxygen tensions greater than 250mmHg are required to halt the alpha toxin production of clostridial infection. This level of tissue oxygen tension can only be achieved with HBOT treatment. (It should be noted that Group A streptococcus produces a toxin similar to the alpha toxin of Clostridium myonecrosis infections.)

Progressive Necrotizing Soft Tissue Infections

Necrotizing soft tissue infection (NSTI) is a set of disorders characterized by a rapidly progressive infection with necrosis or gangrene. No definition of "progressive" was identified. However, definition of NSTI includes progression of infection despite antibiotic therapy. UHMC clinical input speaks to progressive NSTI in terms of NSTI while receiving broad spectrum antibiotics with either performed or planned therapeutic and diagnostic surgical debridement. The UHMC input also notes that frozen section soft-tissue biopsy is the gold standard of diagnosis, but is not feasible in practice.

There are no unique clinical considerations based on the wound characteristics, site and/or depth of infection or time to treatment. By their very nature, NSTI are life and limb threatening.

Idiopathic Sudden Sensorineural Hearing Loss (ISSHL)
Idiopathic sudden sensorineural hearing loss (ISSHL) is an abrupt loss of hearing, typically unilaterally, without a definitive or identifiable cause upon investigation, as is the case for 90% of sudden sensorineural hearing loss patients. The degree of hearing loss is typically defined as a loss of 30 decibels or more across 3 contiguous frequencies on audiogram. The hearing loss initially occurring on one side can occur subsequently on the contralateral side in the future. The exact etiology of ISSHL has not been elucidated but of the major proposed mechanisms may be mitigated by HBOT. ISSHL is included in the FDA approved uses of HBOT.

Central Retinal Artery Occlusion (CRAO) and Other Retinal Conditions
CRAO is relatively rare yet devastating diagnosis with poor prognosis for spontaneous recovery. Factors which influence outcome include the length of time of occlusion, the anatomical site of the occlusion, and the presence of a patent cilioretinal artery. The diagnosis of CRAO is typically and reliably made with a fundoscopic exam. Advanced diagnostic studies can confirm CRAO but are not required for the diagnosis. Treatments for CRAO include ocular massage, anterior chamber paracentesis, fibrinolysis, and ocular pressure lowering agents. However, none of these demonstrate improved outcomes compared to control. The FDA has added CRAO to the list of cleared indications for HBOT.

CRAO is a rare complication associated with CaHA (calcium hydroxylapatite) cosmetic filler injection, likely due to embolism.

In addition to CRAO, there are related clinical syndromes for which HBOT could be considered. This includes individuals with branch retinal artery occlusion, particularly those with complete or near complete blindness in the contralateral eye. Also, Susac's Syndrome which is a rare disorder thought to be an autoimmune endotheliopathy causing vascular injury and deposition of thrombotic material in the lumen of small vessels. Treatments for this syndrome include steroids, anticoagulation, and IVIG; HBOT might improve visual acuity for these individuals.

Acute Peripheral Artery Insufficiency
For this policy review, the indication of acute peripheral artery insufficiency is too broad to include as a stand alone indication for HBOT.

Acute peripheral artery insufficiency is not included in the FDA list of approved conditions for HBOT. The Undersea and Hyperbaric Medical Society guidelines (15th edition) include peripheral artery insufficiency as an indication for HBOT related to diabetic foot ulcers and non-healing arterial insufficiency ulcers but does not have a stand-alone indication for acute peripheral artery insufficiency.

Acute arterial Insufficiencies (AAI) are interruptions, complete or partial, of perfusion that put the tissues distal to the interruption at risk for loss of function or dying. AAIs thereby span all arteries including a variety of conditions already included in this review (e.g., central retinal artery occlusion, ischemic stroke, compartment syndrome). Acute peripheral artery insufficiency (also called peripheral arterial insufficiency) would be a subtype of AAI. Peripheral artery insufficiency is also referred to as peripheral artery disease (PAD). PAD is defined by the American Heart Association as a narrowing of the peripheral arteries that carry blood away from the heart to other parts of the body, and is typically further defined to narrowed arteries reducing blood flow to the arms or legs. The AHA states the most common type of PAD is lower-extremity PAD. In 2024, the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines published a Guideline for the Management of Lower Extremity PAD. The Guideline suggests that HBOT may have a limited role, and states HBOT: ”*may be considered as an adjunctive therapy to revascularization for wound healing in the context of CLTI (chronic limb threatening ischemia) and diabetic foot ulcers”*. No other mention of HBOT is made, including no mention of HBOT for acute limb ischemia.

Timing and Duration of HBOT Treatment
While broad indications are given above, the decision to treat with HBOT and timing of HBOT should be made on a case-by-case basis. For example, acute arterial ischemias have a spectrum of times that vary by tissue type: minutes for neurological tissues, hours for muscle, days for skin and bone, and even longer for relatively avascular connective tissues, cartilage, and adnexal structures. Even for indications with guideline-based time periods there are case studies showing improvement outside of such windows.

For example, the Undersea and Hyperbaric Medical Society Committee recommends HBOT treatment for central retinal artery occlusion (CRAO) within 24 hours of onset, as studies demonstrate the outcome of HBOT is improved with early treatment. However, successful cases have been reported in which treatment began later, sometimes up to weeks later. Given the safety of HBOT, the lack of successful alternative medical treatments, the debilitating impact of vision loss, and the challenges faced in getting a patient to a hyperbaric facility, it is difficult to provide a specific time cutoff after which HBOT should not be tried for CRAO.

As such, no broad statements or specific statements as to timing of HBOT can be provided.
Recommended treatment dose and number of treatment sessions per the UHMS Hyperbaric Oxygen Therapy Committee (15th edition, 2023) include:

- **Acute traumatic ischemia** – there are 3 stages of would healing. Treatment recommended varies based on stage, and ranges from 2-3 times per day for 2-3 days for acute inflammatory stage, 14 days for repair stage, and up to a month for remodeling.
- **Carbon monoxide poisoning** – Use up to 3 ATA for 1 to 3 sessions or to clinical plateau.
- **Central Retinal Artery Occlusion (CRAO)**– Recommend 2 to 2.8 ATA or U.S. Navy Table 6 or equivalent. Treat twice daily to clinical plateau, which typically occurs in less than a week, plus 3 days. Hyperbaric treatments 2-3 times daily may be necessary until the angiogram normalizes or the patient has no further improvement for 3 treatments.

- **Clostridial myositis, Clostridial myonecrosis (Gas gangrene)-** Recommend 3 ATA pressure for 90 minutes, 2-3 times in the first 24 hours, and then 2 times daily for the next 2-5 days. Review is indicated after 10 treatments.
- **Chronic refractory osteomyelitis –** Typically, once daily, 5-7 days per week for 90-120 minutes using 2-3 ATA, and continued for 4-6 weeks. 20-40 sessions typically needed, although might be situations where up to 60 sessions are needed. Patients with refractory stage 3 or 4 osteomyelitis are most likely to benefit from adjunctive hyperbaric oxygen therapy, especially when complicated by adverse local or systemic factors.
- **Compartment syndrome** – Use 2 to 2.4 ATA, usually twice a day for 2 days but sometimes might need 3 times a day. After fasciotomy, twice a day for 7-14 days.
- **Compromised skin grafts and flaps –** Use 2 to 2.5 ATA twice daily for up to 20 sessions.
- **Crush injury** – similar to acute traumatic ischemia above. The UHMS notes that HBOT should be started as close as possible to the time of injury; 3 or more treatments during the first 24 to 72 hours are recommended; 1-2 times per day for 14 days if in the repair phase; daily use for 3-6 weeks during remodeling.
- **Cyanide poisoning** – Patients with cyanide poisoning frequently present with simultaneous carbon monoxide poisoning. Treatment protocol recommended is the same as for carbon monoxide poisoning.
- **Decompression sickness** – Use U.S. Navy Treatment Table 6 or equivalent, typically up to 2.8 ATA, for 1 session up to a clinical plateau. Typically no more than 1 to 2 treatment sessions are needed.
- **Diabetic lower extremity wounds, selected individuals and healing of other problem wounds** –Use 2 to 2.5 ATA daily, should see effects by 2-3 weeks; course of outpatient therapy is typically 30 sessions but might require up to 40 sessions. For HBOT to continue, reevaluation at 30-day intervals must show continued progress in healing.
- **Necrotizing soft-tissue infections** – Use 2 to 2.5 ATA twice daily until stabilization occurs, often occurs within 7-10 treatments. If differential diagnosis includes the possibility of Clostridial myositis and/or myonecrosis and/or remains unclear, 2.8-3 ATA pressures are warranted with 3 treatments in the first 24-48 hours. Avoidance of premature cessation of HBOT is advised, and once extension of necrosis has been halted then once daily treatments over an extended period until the infection is well controlled is recommended. This might require 30 treatments. Review after 30 treatments.
- **Radiation Necrosis** –Most treatments range from 2-2.5 ATA for 40-60 treatments, and review should occur after 60 treatments.
    1. **Mandibular osteoradionecrosis, laryngeal necrosis, other soft tissue head and neck, chest wall necrosis, radiation cystitis, radiation proctitis, miscellaneous abdominal pelvic injuries, cutaneous necrosis** – 2 to 2.4 ATA daily for 90 minutes.
    2. **Neoadjuvant hyperbaric oxygen therapy before dental extractions** – 2 to 2.4 ATA, typically 20 treatments before extraction and 10 treatments after.
- **Sudden sensorineural heating loss** – Recommend 2 to 2.5 ATA for 10 to 20 sessions.
- **Severe Anemia** – Use 2 to 3 ATA for 3 or 4 times a day until there is replacement of red blood cells by regeneration or transfusion.

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: topical and systemic.

Topical Hyperbaric Oxygen Therapy

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.

Systemic Hyperbaric Oxygen Therapy

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.

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 U.S. 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.

As of July 2021, the FDA has cleared hyperbaric chambers for the following disorders:

- Air and gas bubbles in blood vessels
- Anemia (severe anemia when blood transfusions cannot be used)
- Burns (severe and large burns treated at a specialized burn center)
- Carbon monoxide poisoning
- Crush injury
- Decompression sickness (diving risk)
- Gas gangrene
- Hearing loss (complete hearing loss that occurs suddenly and without any known cause)
- Infection of the skin and bone (severe)
- Radiation injury
- Skin graft flap at risk of tissue death
- Vision loss (when sudden and painless in one eye due to blockage of blood flow)
- Wounds (non-healing, diabetic foot ulcers).

HBOT is being studied for other conditions, including COVID-19. However, at this time, the FDA has not cleared or authorized the use of any HBOT device to treat COVID-19 or any conditions beyond those listed above. The website, clinicaltrials.gov, has more information on HBOT clinical trials for COVID-19 and other conditions.

Risks of hyperbaric oxygen therapy

When HBOT chambers are used for indications cleared by the FDA, HBOT is generally safe, and serious complications are rare.

Because of the increased pressure and increased concentration of the oxygen during HBOT, potential risks include:

- Ear and sinus pain
- Middle ear injuries, including tympanic membrane rupture
- Temporary vision changes
- Lung collapse (rare)

High concentrations of oxygen also pose the risk of fire, which is one reason why the FDA recommends treatment at an accredited facility. Explosions and fires have occurred in HBOT chambers that have not been reviewed by the FDA and are located at unaccredited facilities.

Other hyperbaric devices
The FDA has also cleared a large, zippered bag that is intended to treat altitude sickness only.

These zippered chambers for treating altitude sickness provide pressure but do not attach to oxygen tanks. The FDA has not cleared these bags for use with oxygen tanks or oxygen concentrators. However, the FDA is aware of instances in which people used these bags to create homemade HBOT devices, which can pose the risk of fire and suffocation.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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; i.e., the body part to be treated is isolated (e.g., 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.

Summary of Evidence
For individuals with wounds, burns or infections who receive topical hyperbaric oxygen therapy (HBOT), the evidence includes a systematic review, case series, and a randomized controlled trial (RCT). Relevant outcomes are overall survival (OS), symptoms, change in disease status, and functional outcomes. The systematic review identified 3 RCTs including patients with sacral pressure ulcers, ischial pressure ulcers, and refractory venous ulcers. All trials reported that healing improved significantly after HBOT than after standard of care. Pooling of results was not possible due to heterogeneity in patient populations and treatment regimens. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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. Two of the 3 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 an improvement in the net health outcome.

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

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 an 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 that the technology results in an improvement in the net health outcome.

For individuals with acute thermal burns who receive systemic HBOT, the evidence includes a systematic review of 2 RCTs. Relevant outcomes are OS, symptoms, and change in disease status. Both RCTs were judged to have poor methodologic quality. Evidence from well-conducted controlled trials is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with acute surgical and traumatic wounds who receive systemic HBOT, the evidence includes RCTs, controlled nonrandomized studies, and systematic reviews. Relevant outcomes are OS, symptoms, change in disease status, and functional outcomes. There was considerable heterogeneity across the 4 RCTs identified (e.g., patient population, comparison group, treatment regimen, outcomes). This heterogeneity prevented pooling of trial findings and limits the ability to definitively conclude the impact of HBOT on health outcomes for patients with acute surgical and traumatic wounds. Additional evidence from high-quality RCTs is needed. A systematic review of controlled Chinese studies suggests HBOT may increase the survival rate of compromised skin grafts and flaps when initiated within 72 hours; however, risk of bias in the original Chinese publications cannot be evaluated. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

For individuals with necrotizing soft tissue infections who receive systemic HBOT, the evidence includes systematic reviews. Relevant outcomes are OS, symptoms, and change in disease status. A Cochrane review did not identify any RCTs. Another systematic review of retrospective cohort

studies with methodological limitations did not find consistent benefit of adjunctive HBOT use. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with acute coronary syndrome who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are OS, symptoms, change in disease status, and functional outcomes. A Cochrane review identified 6 RCTs. There were 2 pooled analyses, 1 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 that the technology results in an improvement in the net health outcome.

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

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 (e.g., 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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

For individuals with traumatic brain injury who receive systemic HBOT, the evidence includes RCTs and systematic reviews. Relevant outcomes are OS, symptoms, change in disease status, and functional outcomes. RCTs were heterogeneous 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 that the technology results in an improvement in the net health outcome.

For individuals with inflammatory bowel disease who receive systemic HBOT, the evidence includes RCT, observational studies, and a systematic review. Relevant outcomes are symptoms, change in disease status and functional outcomes. Three RCTs have reported mixed findings in patients with ulcerative colitis, with one study terminated early due to futility. 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 that the technology results in an improvement in the net health outcome.

For individuals with idiopathic sudden sensorineural hearing loss who receive systemic HBOT, the evidence includes systematic reviews. Relevant outcomes are symptoms, change in disease status, and functional outcomes. A Cochrane review of RCTs had mixed findings from studies that included individuals with tinnitus. Some outcomes (i.e., 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. A third review found a higher proportion of patients with hearing recovery with HBOT compared to medical treatment alone, but the analysis was limited to 2 RCTs with methodological limitations. One RCT published subsequent to the systematic reviews found a positive effect of HBOT plus steroid combination therapy on measures of auditory function compared to either HBOT or steroids alone, but other outcomes were not reported and the study had numerous relevance, design, and conduct limitations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 (e.g., swelling). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

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 included few RCTs and provide limited evidence on the effect of HBOT. Two RCTs had inconsistent findings. One reported no short-term benefit with HBOT, but some benefits 12 months after radiotherapy; the other did not find a significant benefit of HBOT at 12-month follow-up. Another RCT assessed HBOT for radiation-induced cystitis and found significant benefit by some measures but not others. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 (i.e., 6-week) outcomes. Larger well-conducted RCTs reporting longer-term outcomes are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

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 (i.e., 6-week) outcomes. Additional well-conducted RCTs with longer follow-up are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 (e.g., 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 that the technology results in an improvement in the net health outcome.

For individuals with multiple sclerosis who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms and functional outcomes. A Cochrane review of RCTs did not find a significant difference in Expanded Disability Status Scale scores when

patients with multiple sclerosis were treated with HBOT versus a comparator intervention. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with cancer and are undergoing chemotherapy who receive systemic HBOT, the evidence includes an RCT and a systematic review. Relevant outcomes are OS and change in disease status. While the systematic review reported improvements in tumor control in patients with head and neck cancer who received HBOT, the adverse events accompanying the treatment (e.g., 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 that the technology results in an improvement in the net health outcome.

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.

2024 Input

Clinical input was sought to help determine whether the use of systemic HBOT in individuals with necrotizing soft tissue infections, idiopathic sudden sensorineural hearing loss, central retinal artery occlusion, or acute peripheral artery insufficiency would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 2 respondents, including 2 specialty society-level responses.

For individuals with necrotizing soft tissue infections, idiopathic sudden sensorineural hearing loss, central retinal artery occlusion, or acute peripheral artery insufficiency who receive HBOT, clinical input supports this use provides a clinically meaningful improvement in net health outcomes and indicates this use is consistent with generally accepted medical practice.

2023 Input

Clinical input was sought to help determine whether the use of systemic hyperbaric oxygen therapy (HBOT) in individuals with acute surgical or traumatic wounds and compromised skin grafts or flaps would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 2 respondents, including 2 specialty society-level responses.

For individuals with acute surgical or traumatic wounds and compromised skin grafts or flaps who receive systemic HBOT, clinical input supports this use provides a clinically meaningful

improvement in net health outcomes and indicates this use is consistent with generally accepted medical practice.

2010 Input
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
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Otolaryngology - Head and Neck Surgery
In 2019, the American Academy of Otolaryngology-Head and Neck Surgery updated clinical guidelines on the treatment of sudden sensorineural hearing loss (SSNHL). They give the following options regarding HBOT:

"Clinicians may offer, or refer to a physician who can offer, hyperbaric oxygen therapy (HBOT) combined with steroid therapy within 2 weeks of onset of SSNHL."

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

The guideline provided a comprehensive list of evidence gaps and future research needs on the use of HBOT for SSNHL. These included, among others, the need for a standardized, evidence-based definition of SSNHL, the assessment of the prevalence of SSNHL, and the need for the development of standardized HBOT treatment protocols and standardized outcome assessments.

American College of Cardiology/American Heart Association
In 2024, the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines published a Guideline for the Management of Lower Extremity PAD. The Guideline was developed in collaboration with and endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Podiatric Medical Association, Association of Black Cardiologists, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine, Society for Vascular Nursing, Society for Vascular Surgery, Society of Interventional Radiology, and Vascular & Endovascular Surgery Society. The Guideline included the following statements relevant to this evidence review:

"Beyond wound care, hyperbaric oxygen therapy has been studied in the context of wound healing for CLTI as an adjunctive therapy to revascularization and may have a limited role in this population."

"Hyperbaric oxygen therapy may be considered as an adjunctive therapy to revascularization for wound healing in the context of CLTI (chronic limb threatening ischemia) and diabetic foot ulcers."

American College of Cardiology/American Stroke Association
In 2019 the American Heart Association and American Stroke Association updated the guidelines for early management of acute ischemic stroke. The guidelines were endorsed by the Society for Academic Emergency Medicine, the Neurocritical Care Society, the American Association of Neurological Surgeons, and the Congress of Neurological Surgeons. The Guideline included the following statements relevant to this evidence review:

"The limited data available on the utility of HBO therapy for acute ischemic stroke (not related to cerebral air embolism) show no benefit. HBO therapy is associated with claustrophobia and middle ear barotrauma, as well as an increased risk of seizures. Given the confines of HBO chambers, the ability to closely/adequately monitor patients may also be compromised. HBO thus should be offered only in the context of a clinical trial or to individuals with cerebral air embolism."

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).

Undersea and Hyperbaric Medical Society
In 2015, the Undersea and Hyperbaric Medical Society (UHMS) published guidelines on the use of HBOT for treating diabetic foot ulcers. 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.

The 2023 UHMS Hyperbaric Oxygen Therapy Indications (1 5th edition) included the following indications as recommended:

1. Air or Gas Embolism
2. Arterial insufficiencies: Central Retinal Artery Occlusion; Hyerbaric oxygen Therapy for Selected Problem Wounds
3. Carbon Monoxide Poisoning and carbon monoxide complicated by cyanide poisoning
4. Clostridial Myonecrosis (Gas Gangrene)
5. C Acute Traumatic Ischemias
6. Decompression Sickness
7. Severe anemia
8. Intracranial abscess
9. Necrotizing soft tissue infections
10. Refractory osteomyelitis
11. Delayed radiation injury (soft tissue and bony necrosis)
12. Compromised grafts and flaps
13. Acute thermal burn injury
14. Sudden Sensorineural hearing loss
15. Avascular Necrosis (Aseptic Osteonecrosis).

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

Medicare National Coverage
In 2003 (updated in 2017), 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 3 criteria:
    a. You have type I or type II diabetes and has a lower extremity wound that is due to diabetes;
    b. You have a wound classified as Wagner grade III or higher; and
    c. You have 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 the 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."

Systemic HBOT for other indications is not covered, nor is topical HBOT for any indication.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02407028	Hyperbaric Oxygen Brain Injury Treatment (HOBIT) Trial	200	Jun 2027

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04975867	Targeted Temperature Management Combined With Hyperbaric Oxygen Therapy in Acute Severe Carbon Monoxide Poisoning: Multicenter Randomized Controlled Clinical Trial (TTM-COHB Trial)	46	Jul 2025
NCT05289700	Multicentric, Double-blind, Randomised Controlled Trial of Hyperbaric-oxygen Therapy (HBOT) Versus Placebo for Treating Vaso-Occlusive Crisis (VOC) in Sickle Cell Disease (SCD) After 8 Years Old	100	Mar 2025
bUnpublished			
NCT04193722	The Effect of Hyperbaric Oxygen Therapy on Breast Cancer Patients With Late Radiation Toxicity	189	May 2023

NCT: national clinical trial.

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Policy History

Original Effective Date: 08/25/2003
Current Effective Date: 05/01/2025

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.
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.
04/01/2021	Medical Policy Committee review
04/14/2021	Medical Policy Implementation Committee approval. No change to coverage.
04/07/2022	Medical Policy Committee review
04/13/2022	Medical Policy Implementation Committee approval. No change to coverage.
04/06/2023	Medical Policy Committee review
04/12/2023	Medical Policy Implementation Committee approval. Title changed from "Hyperbaric Oxygen Pressurization (HBO) to "Hyperbaric Oxygen Therapy". Policy statements changed from hyperbaric oxygen pressurization to hyperbaric oxygen therapy. Replaced the heading and coverage statements from "When Services Are Eligible for Coverage" to "When Services May Be Eligible for Coverage" to include criteria. Revised criteria for compromised skin grafts and added information for compromised skin flaps to the criteria. Added information on idiopathic sudden sensorial hearing loss to the criteria. Removed idiopathic sudden sensorial hearing loss from the investigational conditions.
04/04/2024	Medical Policy Committee review
04/10/2024	Medical Policy Implementation Committee approval. Added "not meeting criteria specified in the eligible for coverage statement" to the Acute surgical and traumatic wounds investigational statement. Added "flaps" and additional bullet "visible ischemic changes such as pallor, mottling, or frank necrosis of the overlying skin" to patient selection criteria. Added to deny investigational when criteria are not met.
11/07/2024	Medical Policy Committee review
11/13/2024	Medical Policy Implementation Committee approval. Central retinal artery occlusion added to eligible for coverage statement. Also changed Idiopathic sudden sensorineural hearing loss (ISSHL) in individuals with a loss of 30 decibels or more or hearing loss at least 61 decibels of pure tone thresholds when HBOT is combined with steroid therapy (systemic or intra-tympanic) and initiated within 1 month of onset of SSNHL. Added "Peripheral arterial insufficiency related to non-healing arterial insufficiency ulcers with no measurable signs of healing after 30 days of an adequate course of standard wound therapy" as eligible. Under the investigational section, "Acute peripheral artery insufficiency (outside of other listed medically necessary indications involving arterial insufficiency) (see Policy Guidelines)" was added and "Retinal artery insufficiency, acute" was deleted.
04/03/2025	Medical Policy Committee review
04/09/2025	Medical Policy Implementation Committee approval. FDA information updated.

Next Scheduled Review Date: 04/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 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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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	All related Diagnoses

*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 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: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.