Protocol

Hyperbaric Oxygen Therapy

(20104)

Medical Benefit		**Effective Date**: 06/01/19	**Next Review Date**: 03/21
Preauthorization	Yes	**Review Dates**: 07/07, 07/08, 09/09, 05/10, 05/11, 05/12, 05/13, 05/14, 05/15, 11/15, 11/16, 03/17, 03/18, 03/19, 03/20	

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With wounds, burns, or infections	Interventions of interest are: • Topical hyperbaric oxygen therapy	Comparators of interest are: • Dressings • Débridement • Medication	Relevant outcomes include: • Overall survival • Symptoms • Change in disease status • Functional outcomes
Individuals: • With chronic diabetic ulcers	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Standard wound care • Advanced wound therapy	Relevant outcomes include: • Symptoms • Change in disease status
Individuals: • With carbon monoxide poisoning	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Breathing oxygen at standard pressure	Relevant outcomes include: • Overall survival • Symptoms
Individuals: • With radionecrosis, osteoradionecrosis, and treatment of irradiated jaw	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Débridement • Medication	Relevant outcomes include: • Symptoms • Change in disease status
Individuals: • With chronic refractory osteomyelitis	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Medication • Surgical therapy	Relevant outcomes include: • Symptoms • Change in disease status
Individuals: • With acute thermal burns	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Cooling therapy • Medication	Relevant outcomes include: • Overall survival • Symptoms • Change in disease status
Individuals: • With acute surgical and traumatic wounds	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Dressings • Débridement • Medication	Relevant outcomes include: • Overall survival • Symptoms • Change in disease status
Individuals: • With bisphosphonate-related osteonecrosis of the jaw	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Medication • Surgical therapy	Relevant outcomes include: • Symptoms • Change in disease status

Populations	Interventions	Comparators	Outcomes
Individuals: • With necrotizing soft tissue infections	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Medication • Surgical therapy	Relevant outcomes include: • Overall survival • Symptoms • Change in disease status
Individuals: • With acute coronary syndrome	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Medication • Surgical therapy	Relevant outcomes include: • Overall survival • Symptoms • Change in disease status • Functional outcomes
Individuals: • With acute ischemic stroke	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Tissue plasminogen activator • Endovascular procedure	Relevant outcomes include: • Overall survival • Symptoms • Change in disease status • Functional outcomes
Individuals: • With motor dysfunction associated with stroke	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Physical therapy	Relevant outcomes include: • Symptoms • Functional outcomes
Individuals: • With Bell palsy	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Self-care (e.g., artificial tears, eyepatch) • Medication	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • With traumatic brain injury	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Medication • Surgical therapy • Rehabilitation	Relevant outcomes include: • Overall survival • Symptoms • Change in disease status • Functional outcomes
Individuals: • With inflammatory bowel disease	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Medication • Surgical therapy	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • With idiopathic sudden sensorineural hearing loss	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Medication • Surgical therapy	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • With delayed-onset muscle soreness	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Conservative care (e.g., massage) • Medication	Relevant outcomes include: • Symptoms • Functional outcomes
Individuals: • With autism spectrum disorder	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Behavioral therapy • Medication	Relevant outcomes include: • Symptoms • Functional outcomes
Individuals: • With cerebral palsy	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Physical therapy • Medication	Relevant outcomes include: • Symptoms • Functional outcomes
Individuals: • With vascular dementia	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Rehabilitation • Medication	Relevant outcomes include: • Symptoms • Functional outcomes
Individuals: • With radiotherapy adverse events	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Medication	Relevant outcomes include: • Symptoms • Functional outcomes

Populations	Interventions	Comparators	Outcomes
Individuals: • With idiopathic femoral neck necrosis	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Physical therapy • Medication • Surgical therapy	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • With migraine	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Medication	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • With herpes zoster	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Medication	Relevant outcomes include: • Symptoms • Change in disease status
Individuals: • With fibromyalgia	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Medication	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • With multiple sclerosis	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Behavioral therapy • Medication	Relevant outcomes include: • Symptoms • Functional outcomes
Individuals: • With cancer who are undergoing radiotherapy or chemotherapy	Interventions of interest are: • Systemic hyperbaric oxygen therapy	Comparators of interest are: • Chemotherapy without hyperbaric oxygen therapy	Relevant outcomes include: • Overall survival • Change in disease status

DESCRIPTION

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 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 three 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 two 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 two RCTs. Relevant outcomes are overall survival, symptoms, and change in disease status. Only two 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 four RCTs identified (e.g., 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 three-month follow-up; however, there were no significant benefits of HBOT for most health outcomes compared with standard care in the long-term (six months to two 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 pa-

tients 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 six RCTs. There were two 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 three-six 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 two 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 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 (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. 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 (e.g., 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 two 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 two 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 (i.e., six-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 three of the 11 trials. Meta-analysis of these three 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 (i.e., six-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 two 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 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 (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 the effects of the technology on health outcomes.

POLICY

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

Systemic hyperbaric oxygen pressurization may be considered **medically necessary** in the treatment of the following conditions:

- non-healing diabetic wounds of the lower extremities in patients who meet the following three criteria:
  a) patient has type 1 or type 2 diabetes and has a lower extremity wound due to diabetes;
  b) patient has a wound classified as Wagner grade 3 or higher (see Policy Guidelines); and
  c) patient has no measurable signs of healing after 30 days of an adequate course of standard wound therapy;
- acute traumatic ischemia (e.g., crush injuries, reperfusion injury, compartment syndrome);
- decompression sickness;
- gas embolism, acute;
- cyanide poisoning, acute;
- acute carbon monoxide poisoning;
- soft-tissue radiation necrosis (e.g., radiation enteritis, cystitis, proctitis) and osteoradionecrosis;
- pre- and post-treatment for patients undergoing dental surgery (non-implant-related) of an irradiated jaw;
- gas gangrene (clostridial myonecrosis);
- profound anemia with exceptional blood loss: only when blood transfusion is impossible or must be delayed; and
- chronic refractory osteomyelitis.

Hyperbaric oxygen pressurization is considered **investigational** in all other situations, including but not limited to, the treatment of the following conditions:

- compromised skin grafts or flaps;
- acute osteomyelitis;
- bisphosphonate-related osteonecrosis of the jaw;

- necrotizing soft tissue infections;
- 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 (e.g., multiple sclerosis, amyotrophic lateral sclerosis);
- retinal artery insufficiency, acute;
- retinopathy, adjunct to scleral buckling procedures in patient with sickle cell peripheral retinopathy and retinal detachment;
- pyoderma gangrenosum;
- acute arterial peripheral insufficiency;
- 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;
- radiation-induced injury in the head and neck, except as noted earlier in the medically necessary statement;
- 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 (i.e., posttraumatic stress disorder, generalized anxiety disorder or depression).

POLICY GUIDELINES

TOPICAL HYPERBARIC OXYGEN

Topical hyperbaric oxygen is administered with 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 protocol addresses topical 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 four consecutive days. After a three-day break, the cycle is repeated. The regimen may last for eight 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.

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.

MEDICARE ADVANTAGE

For Medicare Advantage, the above **medically necessary** policy statements and guidelines apply with these additional conditions:

- Progressive necrotizing infections (necrotizing fasciitis),
- Acute peripheral arterial insufficiency,
- Preparation and preservation of compromised skin grafts (not for primary management of wounds),
- Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment,
- Osteoradionecrosis as an adjunct to conventional treatment,
- Suturing of severed limbs.

BACKGROUND

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 one 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%.[1] 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.

REGULATORY STATUS

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.[2] 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.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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