

Corporate Medical Policy

Hyperbaric Oxygen Therapy (HBOT)

Description of Procedure or Service

Systemic Hyperbaric Oxygen Therapy (HBOT): The medical use of oxygen administered in a single or multiple person chamber where the individual breathes 100% oxygen that is pressurized at 1.4-3.0 atmospheres absolute (atm abs). The goal of treatment is to increase oxygen levels in the individual's systemic circulation. During HBOT, individuals breathe pure oxygen gas at a pressure that is typically 2 to 3 times greater than the atmospheric pressure. The elevated concentration and pressure of the oxygen allows higher levels of oxygen absorption by the blood, creating hyperoxygenation in the tissues. HBOT may be used in certain emergent situations or in the treatment of certain chronic conditions. These physiologic benefits of HBOT not only cause immediate improvement in tissue perfusion and oxygenation, but can also create a sustained advantage for wound healing process. 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 individual receives pure oxygen by mask, head tent, or endotracheal tube.

Background

Hyperbaric oxygen therapy (HBOT) is defined as systemic treatment in which the entire individual is placed inside a pressurized chamber and breathes 100% oxygen under a pressure greater than 1 atmosphere (atm). It is used to treat certain diseases and conditions that may improve when an increased partial pressure of oxygen is present in perfused tissues.

The literature states that HBOT should not be a replacement for other standard successful therapeutic measures. Depending on the response of the individual and the severity of the original problem, treatment may range from less than 1 week to several months' duration, the average being 2 to 4 weeks. Hyperbaric oxygen therapy for more than 2 months is usually not necessary.

Acute air or gas embolism: Early hyperbaric treatment is considered a standard of care and can completely reverse the condition. An observational study of 5269 cases of decompression illness found that a longer delay in treatment resulted in a lower rate of complete recovery (94% complete recovery at 1-6 hour delay compared to 76% complete recovery at greater than 36 hour delay).

Arterial perfusion and wound healing: The hypoxic nature of all wounds has been demonstrated and the hypoxia, when pathologically increased, correlates with impaired wound healing and increased rates of wound infection. Local oxygen tensions in the vicinity of the wound are approximately half the values observed in normal, non-wounded tissue. The rate at which normal wounds heal has been shown to be oxygen dependent. Fibroblast replication, collagen deposition, angiogenesis, resistance to infection, and intracellular leukocyte bacterial killing are oxygen sensitive responses essential to normal wound healing. However, if the periwound tissue is normally perfused, steep oxygen gradients from the periphery to the hypoxic wound center support a normal wound healing response. Regardless of the

primary etiology of problem wounds, a basic pathway to non-healing is the interplay between tissue hypoperfusion, resulting hypoxia, and infection. A large body of evidence exists which demonstrates that intermittent oxygenation of hypo-perfused wound beds, a process only achievable in selected patients by exposing them to hyperbaric oxygen treatment, mitigates many of these impediments and sets into motion a cascade of events that leads to wound healing.

Carbon monoxide poisoning: Studies have shown that hyperbaric or high-flow normobaric oxygen is recommended for the treatment of acute carbon monoxide poisoning. One trial reported improved cognitive outcomes when 3 hyperbaric oxygen treatments were given in a 24 hours period.

Central retinal artery occlusion: Evidence based literature finds that although hyperbaric oxygen therapy may prevent permanent visual loss if administered within 24 hours of the onset of acute visual loss, the evidence supporting its efficacy is only fair to good and is based upon retrospective case studies, not randomized controlled trials.

Profound anemia: Blood transfusion is the standard of care for anemic conditions however, studies have found that hyperbaric oxygen therapy is an effective option for patients with medical barriers or personal objections to blood transfusion therapy.

Idiopathic sudden sensorineural hearing loss: Studies have shown improved hearing associated with profound hearing loss if hyperbaric oxygen therapy was initiated within 10 days. However, there is no evidence supporting the use of hyperbaric oxygen therapy for chronic idiopathic sensorineural hearing loss (greater than 6 months from onset).

Intracranial abscess: Evidence demonstrates a positive outcome with the use of hyperbaric oxygen therapy for intracranial abscesses with the following characteristics: multiple abscesses, deep or dominant location, immunocompromised host, contraindication to surgery and no clinical response/clinical deterioration after surgical intervention and antibiotic therapy. Case studies suggest decreased mortality with the use of hyperbaric oxygen therapy.

The one absolute contraindication to hyperbaric oxygen treatment is a patient with an untreated pneumothorax. All patients should have lung imaging before treatment. If a patient receives treatment for a pneumothorax, the risk-benefit ratio would need evaluation before placing the patient in the chamber based on their indication. During pneumothorax management, a chest tube with the Heimlich valve open prior to initiation of treatment would be an acceptable approach for pre-chamber management in an emergency clinical situation.

Relative contraindications to evaluate before treatment include, but are not limited to, the following:

- Uncontrolled hypertension (blood pressure can increase during treatment)
- Diabetes mellitus with glucose levels greater than 300 or less than 100
- Congestive heart failure with ejection fraction less than 35% (hyperbaric can exacerbate congestive heart failure and/or flash pulmonary edema)
- Claustrophobia/confinement anxiety (more common in monoplace chambers, may require multiplace chamber or pharmacotherapy to tolerate treatments)
- Congenital spherocytosis (hyperbaric oxygen can cause severe hemolysis)

- Current upper respiratory infection (concern for ability to equalize on the descent, or risk of reverse sinus block on the ascent, both of these situations can lead to barotrauma)
- Fever (can lower the seizure threshold during treatment)
- Chronic sinus condition (concern for ability to equalize on the descent, or risk of reverse sinus block on the ascent, both of these situations can lead to barotrauma)
- Pacemaker/implantable device (possibility of malfunction under pressure, if device delivers a shock in 100% oxygen environment could ignite a fire, need to coordinate with the safety officer and call manufacturer to make sure device has been pressure tested to the treatment depth you are going to recommend)
- Recent eye/retinal/cataract surgery or optic neuritis (buckle procedure can have air trapped, other procedures can leave bubbles inside and usually require a few months waiting period before initiation of treatment)
- Recent thoracic surgery (recommend imaging to rule out pneumothorax)
- Obstructive lung disease/chronic obstructive pulmonary disease(COPD)/asthma (lose the hypoxic drive to breathe, can screen with pulmonary function tests and xenon washout study to evaluate for risk of air trapping)
- History of seizures (recommend that the seizures need to be controlled before initiation of treatment, monitor therapeutic levels, may require lower treatment pressures)
- Untreated cancer (controversial topic, but there are no studies to date showing that hyperbarics promote malignant cell proliferation)
- Contact lenses (need to be gas permeable, no hard contact lenses)
- Pregnancy

Regulatory Status

The FDA has approved a number of hyperbaric chambers since 1984 through a 510(k) process as Class II devices for the indications listed as appropriate by the Hyperbaric Oxygen Therapy Committee of the Undersea & Hyperbaric Medical Society.

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

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

Benefit Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits.

Following the initial 20-session treatment period or within any 30-day treatment period, continued systemic HBOT is considered medically necessary when MEASURABLE signs of healing have been demonstrated and documented. When medical necessity is documented and prior authorization is obtained, additional sessions will be authorized up to a maximum of 60 sessions per calendar year.

Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Policy Statement

GEHA will provide coverage for Hyperbaric Oxygen Therapy when it is determined to be medically necessary because the medical criteria and guidelines as documented below have been demonstrated.

When treatment for hyperbaric oxygen therapy is covered:

1. Acute air or gas embolism
2. Acute peripheral arterial insufficiency
3. Acute traumatic peripheral ischemia (e.g. crush injuries and suturing of severed limbs, reperfusion injury; compartment syndrome)
4. Carbon monoxide poisoning
5. Central retinal artery occlusion (CRAO), acute treatment
6. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management, including a six- week course of parenteral antibiotics and at least one surgical eradication/debridement attempt, unless contraindicated, with photograph (with ruler) of wound plus X-ray or bone culture documenting diagnosis.
7. Compromised skin grafts and flaps
8. Thermal burns
9. Cyanide poisoning (with co-existing carbon monoxide poisoning)
10. Decompression illness
11. Profound Anemia with exceptional blood loss only when blood transfusion is impossible because there is no suitable blood available, or religion does not permit transfusions
12. Gas gangrene (Clostridial myositis and myonecrosis)
13. Idiopathic sudden sensorineural hearing loss (SSHL) -- SSHL greater than 30 dB affecting greater than 3 consecutive frequencies of pure-tone thresholds when member has failed oral and intra-tympanic steroids, and HBOT is initiated within 3 months after onset
14. Intracranial abscess (Actinomyces)
15. Necrotizing soft tissue infection (necrotizing fasciitis)
16. Soft Tissue radiation necrosis and osteoradionecrosis
17. Pre-treatment and post-treatment for individuals undergoing dental surgery
18. Non-healing Diabetic wounds of the lower extremities in members who have:
 - Type I or type II diabetes and a lower extremity wound due to diabetes
 - Wound classified as Wagner grade 3 or higher; and
 - No measureable signs of healing after 30 days of an adequate course of standard wound therapy: including but not limited to assessment and treatment of associated vascular insufficiencies; optimized nutritional status; optimized glucose control; necrotic tissue debridement; maintenance of clean, moist wound bed and appropriate dressing; appropriate offloading; and treatments to resolve infections.

- 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 HBOT. Continued treatment with HBOT is not considered medically necessary if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

Table: Wagner Grading System

Grade 0: Intact skin
Grade 1: Superficial diabetic ulcer
Grade 2: Ulcer extensionInvolves ligament, tendon, joint capsule or fascia; no abscess or osteomyelitis
Grade 3: Deep ulcer with abscess, infectious tendonitis, or osteomyelitis
Grade 4: Gangrene to portion of forefoot
Grade 5: Extensive gangrene of foot

Source: Wagner, 1987.

Requirements for documentation of Grade 3 Wagner lesion: For documentation of presence of abscess, medical record should note the presence of some fluid release during the course of a surgical debridement or incision. For documentation of osteomyelitis, X-rays or culture are required. For infectious tendonitis, clinical observation (rubor, calor, discharge) with photographic documentation or culture is required.

When treatment for hyperbaric oxygen therapy is not covered:

1. GEHA considers systemic HBOT experimental and investigational for members with any of the following contraindications to systemic HBOT, as the safety of systemic HBOT for persons with these contraindications to HBOT has not been established:
 - A. Concurrent administration of doxorubicin, cisplatin, or disulfiram
 - B. Premature infants (birth prior to 37 weeks gestation)
 - C. Untreated pneumothorax
 - D. Active cancer
 - E. Active untreated seizures
 - F. Obstructive lung disease, upper respiratory or sinus infections
 - G. Recent ear surgery or injury
 - H. Fever
 - I. Claustrophobia
2. GEHA considers Topical HBOT (A4575; E0446) directly administered to the open wound, and limb-specific hyperbaric oxygen pressurization in small limb-encasing devices experimental and investigational because its efficacy has not been established through well-controlled clinical trials.
3. GEHA considers the use of systemic HBOT experimental and investigational for the following conditions (not an all-inclusive list) because there is insufficient evidence in the medical literature establishing that systemic HBOT is more effective than conventional therapies:
 - A. Acute or chronic cerebral vascular insufficiency
 - B. Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary

- C. Acute cerebral edema
- D. Aerobic septicemia
- E. Anaerobic septicemia and infection other than clostridial
- F. Arthritic Diseases
- G. Autism
- H. Brain injury
- I. Cardiogenic shock
- J. Cerebral Palsy
- K. Chronic pain (e.g., cluster headaches, fibromyalgia, migraines, trigeminal neurologia)
- L. Chronic peripheral vascular insufficiency
- M. Cutaneous, decubitus, and stasis ulcers
- N. Hepatic necrosis
- O. Lyme's Disease
- P. Multiple Sclerosis.
- Q. Myocardial infarction
- R. Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease)
- S. Organ storage
- T. Organ transplantation
- U. Pulmonary emphysema
- V. Senility
- W. Sickle cell anemia
- X. Stroke
- Y. Systemic aerobic infection
- Z. Tetanus

Policy Guidelines

HBOT should not be a replacement for successful standard therapeutic measures. Documentation in the medical record should support the specific condition being treated with HBOT and the medical necessity of such treatment.

The Food and Drug Administration (FDA) has approved 14 specific conditions for HBOT. The Centers for **Medicare & Medicaid** Services (CMS) has published a national coverage determination (NCD) outlining specific coverage criteria for HBOT (National Coverage Determination (NCD) for HYPERBARIC Oxygen Therapy (20.29).

Covered codes:

99183	Physician or other qualified health care professional, attendance and supervision of hyperbaric oxygen therapy, per session
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval

Physician (or required) documentation:

GEHA considers outpatient, systemic HBOT medically necessary WITH prior authorization when ALL of the following Plan criteria are met, as specified below in items 1 through 4:

1. A treatment plan, including the goal of the therapy and proposed number of treatments, has been submitted to the Plan for review; AND
2. The treatment is evaluated at least every 20 treatments and/or at least every 30 days during administration of systemic HBOT, and the reevaluation shows continued progress/healing with treatment; AND
3. The member is age 18 or older on the date of service: AND
**NOTE: Plan Medical Director Review is required for approval of HBOT administered on a member under the age of 18 on the date of service.
4. The member has at least ONE (1) of the covered conditions, as noted above

Plan Medical Director Review Required:

1. Plan Medical Director Review is required for individual consideration when measurable signs of healing are NOT documented or for a covered condition not specified above.
2. Plan Medical Director review is required for approval of systemic HBOT administered to a member under the age of 18 on the date of service
3. Plan Medical Director review is required for approval of systemic HBOT administered to a member when applicable criteria in the Medical Policy Statement section of this policy are NOT met including any treatments > 60 sessions per calendar year.

Scientific References

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Compliance-Programs/Prior-Authorization-Initiatives/Downloads/HBOPriorAuth_OperationalGuide_111816.pdf

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Policy implementation and updates

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