Hyperbaric Oxygen Therapy

Clinical Coverage Criteria

Overview

Hyperbaric oxygen therapy (HBOT) is a treatment during which a patient breathes 100% pure oxygen while inside a treatment chamber at 1.4 atmosphere absolute (ATA) or greater.

During HBOT, the patient breathes 100% oxygen, creating oxygen-rich, nitrogen-poor blood. This creates a gradient of nitrogen between the blood and the bubble, causing nitrogen to efflux from the bubble into the bloodstream, which, in effect, makes the bubble smaller. For other conditions, the therapeutic value of HBOT is its ability to drastically increase partial pressure of oxygen in the tissues of the body. The oxygen partial pressures achievable using HBOT is much higher than those achievable while breathing pure oxygen at normobaric conditions (i.e. at normal atmospheric pressure). A related effect is the increased oxygen transport capacity of the blood. Under normal atmospheric pressure, oxygen transport is limited by the oxygen binding capacity of hemoglobin in red blood cells and very little oxygen is transported by blood plasma. Because the hemoglobin of the red blood cells is almost saturated with oxygen under atmospheric pressure, this route of transport cannot be exploited any further. Oxygen, carried by plasma under hyperbaric conditions is greatly increased. HBOT is delivered via monoplace or multiplace chambers (monoplace chambers are designed to accommodate one person, multiplace chambers are designed to accommodate two or more people). Hyperbaric oxygen chambers are Class II devices reviewed by the FDA under the 510(K) pre-market approval process for the treatment of indications recommended by the Undersea and Hyperbaric Medical Society (UHMS). The following are recommended uses of HBOT as defined by the Hyperbaric Oxygen Therapy Committee of the UHMS (www.uhms.org): Undersea and Hyperbaric Medical Society.

1. Air or Gas Embolism
2. Carbon Monoxide Poisoning, Carbon Monoxide Poisoning Complicated By Cyanide Poisoning
3. Clostridial Myositis and Myonecrosis (Gas Gangrene)
4. Crush Injury, Compartment Syndrome and Other Acute Traumatic Ischemias
5. Decompression Sickness
6. Arterial Insufficiencies: Central Retinal Artery Occlusion, Enhancement of Healing In Selected Problem Wounds
7. Severe Anemia
8. Intracranial Abscess
9. Necrotizing Soft Tissue Infections
10. Osteomyelitis (Refractory)
11. Delayed Radiation Injury (Soft Tissue and Bony Necrosis)
12. Compromised Grafts and Flaps
13. Acute Thermal Burn Injury
14. Idiopathic Sudden Sensorineural Hearing Loss

HBOT is delivered across a range of settings including but not limited to hospitals, outpatient medical clinics, independent hyperbaric clinics, commercial facilities (such as oil and natural gas drilling rigs), military bases, and veteran's hospitals. Only hospital-based, outpatient medical clinics and independent hyperbaric clinics provide HBOT to the general patient population.

- Hospital-based (located on the hospital's main campus) – provide HBOT to both inpatients and outpatients for most if not all FDA-approved indications. Some hospitals specialize in providing HBOT in emergency situations, some have the ability to handle mass casualties; others do not provide emergency treatment but focus on conditions that require specialty care. Some hospitals have multiplace hyperbaric chambers so that nursing and other staff can accompany critical patients inside the chamber.
- Outpatient medical clinics – provide outpatient treatment for a limited number of FDA-approved indications, such as chronic wounds and radionecrosis. These clinics are affiliated with a hospital, medical center or healthcare delivery system but physically removed from the hospital's main campus.
- Independent hyperbaric clinics – freestanding facilities that operate independently in physician's offices or other commercial buildings. These facilities treat a both FDA-approved and off-label indications.

Policy

Fallon Health requires Prior Authorization for non-emergency uses of Hyperbaric Oxygen Therapy. Fallon Health covers the recommended uses of HBOT defined by the Hyperbaric Oxygen Therapy Committee of the Undersea and Hyperbaric Medical Society (UHMS).

All of the following Guidelines for HBOT and the applicable medical necessity criteria must be met to satisfy coverage requirements for HBOT:

1. For the purposes of coverage, HBOT is defined as a treatment during which a patient breathes pure 100% oxygen while inside a treatment chamber at 1.4 atmosphere absolute (ATA) or greater.

2. Direct supervision by an appropriately certified/trained physician or non-physician practitioner NPP) is required for coverage.
    - For hospital-based HBOT chambers, direct supervision means the physician or NPP must be present in the hospital and immediately available to furnish assistance and direction throughout the performance of the procedure. Immediately available means immediate physical presence, and while immediate is not defined in terms of time or distance, the general definition of the work means "without interval of time." Therefore, the supervising physician or NPP could not be performing another procedure or service that he or she could not interrupt.
    - For outpatient medical clinics and independent hyperbaric clinics, direct supervision means that the supervising physician or NPP must be present in the clinic and immediately available to furnish assistance and direction throughout the performance of the procedure. This does not mean that the physician or NPP must be present in the room where the procedure is being performed.

3. HBOT is performed in the setting of a hospital, either inpatient or outpatient. This is predicated upon the potential need for intensive care level services and or advanced cardiac life support (ACLS) should a complication occur in the delivery of HBOT. Fallon Health expects that the hospital that provides the setting for the delivery of HBOT has completed the process of physician credentialing. Fallon Health will cover HBOT when performed in a non-hospital setting (outpatient medical clinic or independent hyperbaric clinic) when the following criteria are met:
    - Direct supervision is provided by a physician or NPP certified/trained in HBOT delivery and ACLS, and
    - The facility must be equipped to provide an emergent airway and ACLS should a complication occur.

4. The plan member does not have an absolute contraindication to HBOT. Absolute contraindications include:
    - Untreated pneumothorax
    - Prior treatment with bleomycin (tradename Blenoxane). Case reports exist of patients previously treated with bleomycin being exposed to hyperoxia during general anesthesia subsequently developing fatal respiratory distress syndrome. Largely as a result of these case reports previous bleomycin exposure is considered by many as an absolute contraindication to HBOT. Some authors believe that bleomycin should be considered a relative and not an absolute contraindication to HBOT. Small numbers of patients previously treated with bleomycin have been uneventfully treated with HBOT and many have successfully undergone general anesthesia. To make a rational risk versus benefit decision we must consider in detail what the current evidence suggests in regards to the general risks of bleomycin and HBOT and whether it is possible to risk stratify patients previously treated with bleomycin identifying those at high risk of an adverse outcome. Factors such as time elapsed since bleomycin treatment, the total dose, evidence of pulmonary complications and the patients creatinine clearance all need considering.
    - Concomitant treatment with cisplatinor doxorubicin. HBOT may be considered after these chemotherapeutic agents have been discontinued.
    - Concomitant use of disulfiram.
    - Pregnancy (the only exception should be a serious life-threatening situation, like gas gangrene, necrotizing fasciitis, or carbon monoxide poisoning).

5. The plan member does not have a relative contraindication to HBOT or if the plan member has a relative contraindication to HBOT it has been documented by the ordering physician that the benefit of HBOT outweighs the risks. Relative contraindications include:
    - Asthma
    - Claustrophobia
    - Congenital spherocytosis
    - Chronic obstructive pulmonary disease
    - Eustachian tube dysfunction
    - High fever
    - Pacemakers or epidural pain pumps
    - Seizures
    - Upper respiratory infection

HBOT is covered for the following non-emergent medical conditions, when the Guidelines for HBOT and the medical necessity criteria listed in the below table are met. Treatment regimens for these conditions vary. HBOT will be authorized for a maximum of 30 treatments. Continued treatment with HBOT requires evidence of compliance with and benefit from the prescribed treatment regimen.

<u>Chronic refractory osteomyelitis:</u>
Refractory osteomyelitis is defined as chronic osteomyelitis that persists following appropriate medical and surgical interventions. Such interventions include the use of antibiotics, aspiration of abscess, immobilization of the affected extremity, and surgery. The UHMS recommends that HBOT be used in patients with Cierny-Mader classification stage 3B and 4B osteomyelitis and in conjunction with the above medical and surgical treatments.

- HBOT is considered a medically necessary adjunct treatment for chronic refractory osteomyelitis, i.e., patients with Cierny-Mader classification stage 3B and 4B osteomyelitis.

- Treatment depends on the severity of the patient's clinical disease. Patients with chronic refractory osteomyelitis are usually treated at 2.0 to 2.5 ATA for 90-120 minutes per day, 5 days per week and typically receive 20-40 treatments over a 4 to 6 week period.
- Patients with Cierny-Mader Stage 1 and 2 are primarily treated with antibiotics and limited surgical debridement. HBOT is not recommended for these patients.

Delayed radiation injury (soft tissue and bony necrosis):
Delayed radiation injuries are typically seen after a latent period of six months or more and may develop many years after the radiation exposure. Sometimes, acute or subacute injuries are so severe that they never resolve and evolve to become chronic injuries indistinguishable from delayed radiation injuries. These are termed consequential effects and are not characterized by a symptom-free latent period. While uncommon, these delayed injuries can cause devastating chronic debilitation to patients. Notably, they can be quiescent until an invasive procedure is performed in the radiation field. Delayed radiation injuries are generally divided into soft tissue and hard tissue radionecrosis.

HBOT is considered a medically necessary adjunct treatment for the following delayed radiation injuries:

1. Radiation-induced hemorrhagic cystitis: A particularly debilitating soft tissue radionecrosis occurs in the bladder with hemorrhagic cystitis. Secondary infection is almost always present. None of the earlier therapies such as the intravascular instillation of formalin or silver nitrate, the systemic use of steroids or antibiotics, the hydrostatic dilatation of the bladder, or the bilateral ligation of the hypogastric arteries proved effective in studies.
2. Radiation-induced enteritis/proctitis: Radiation therapy to the pelvis can cause late effects to intestinal tissues. Chronic radiation enteritis develops in 4% to 22% of patients after treatment. The symptoms are frequently disabling and may be progressive, including bleeding, ulceration, fistulas, strictures, and intestinal obstruction. Depending on the site of radiation injury, a latency period of 3 to 12 months may be seen. Usual medical management of radiation enteritis or proctitis includes: systemic or topical steroids, antibiotics, pain control, and barrier agents.
3. Mandibular osteoradionecrosis: Radiation therapy is a major therapeutic modality for the management of head and neck cancers, administered as a primary, adjuvant, or palliative therapy. The mandible, or lower jaw, is the most common site of radiation-induced tissue damage following treatment of these cancers, with an incidence of 5% to 15%. The diagnosis of osteoradioecrosis depends primarily on clinical and radiographic changes in the bone, and the typical signs and symptoms include ulceration of the mucosa, loosening of the teeth (in the case of mandibular osteoradioecrosis), and exposure of the necrotic bone with development of a chronic non-healing wound.

Patients are treated as follows:

- Stage I – Primary HBOT therapy, regardless of prior treatment. Begin with 30 HBOT treatments at 2.4 ATA for 90 minutes. If no improvement, advance to Stage II. If improvement, give 10 additional HBOT treatments. Stage I responders demonstrate a softening of the radiated tissues and spontaneous sequestration of the exposed bone with formation of granulation tissue.
- Stage II – Surgical debridement (transoral resection/alveolar sequestrectomy) of nonviable bone and additional HBOT. Patients have an amount of nonviable bone in excess of that capable of resorption and sequestration from HBOT-induced angiogenesis alone. Surgery must maintain mandibular continuity and not compromise blood supply of adjacent viable, but radiation-damaged bone,

but may include extraction of involved dentition. If no improvement, advance to Stage III. If improvement, give 10 additional (postoperative) HBOT treatments. Tissues that heal without complication are challenged with a prosthesis, as are tissues in Stage I responders.

- Stage III – More extensive resection (continuity resection) with additional HBOT and secondary delayed reconstruction. Patients represent those with a greater quantity of nonviable bone and/or soft tissue unable to be managed by HBOT-induced angiogenesis alone or HBOT combined with local sequestrectomy. Minimum of 30 preoperative dives. Postoperative treatment: give 10 additional HBO treatments.
- Stage IV – Reconstruction: 10 weeks after successful resolution of mandibular ORN: 20 preoperative dives, then reconstruction with bone graft, then 10 postoperative dives.

<u>Compromised skin grafts and flaps (i.e., preexisting grafts or flaps that are showing signs of failure or necrosis):</u>

A skin graft is a transplanted tissue without its blood supply which is transferred during skin grafting surgery, a type of surgical grafting where transplantation of skin is performed. A skin flap differs from graft in that it is a section of tissue that comes with its original blood supply. HBOT is neither necessary nor recommended for the support of normal, uncompromised grafts or flaps. However, in tissue compromised by irradiation or in other cases where there is decreased perfusion or hypoxia, HBOT has been shown to be extremely useful in flap salvage. Hyperbaric oxygen can help maximize the viability of the compromised tissue thereby reducing the need for regrafting or repeat flap procedures. The criteria for selecting the proper patients that are likely to benefit from adjunctive hyperbaric oxygen for graft or flap compromise is crucial for a successful outcome. Identification of the underlying cause for graft or flap compromise can assist in determining the proper clinical management and use of hyperbaric oxygen therapy.

HBOT is considered a medically necessary adjunct treatment for compromised skin grafts and flaps.

- Clinical opinion varies as to what constitutes an appropriate timeframe of when to utilize HBOT as an intervention. Many failing or compromised grafts/flaps present within 2 weeks of the procedure. To be maximally effective, HBOT should be started as soon as signs of flap compromise appear.
- The current standard for HBOT to treat a compromised graft or flap 90-120 minutes twice daily at 2.0 to 2.5 ATA until the graft or flap appears viable and then once per day until completely healed. In general, benefit should be seen by 20 treatments. (Hyperbaric Oxygen Therapy Committee Report 2003 - Skin Grafts and Flaps)
- HBOT may be used to prepare an already compromised recipient site for a new graft or flap.
- HBOT is not covered for the initial preparation of a base for skin grafting or for normal, uncompromised skin grafts.

<u>Wagner grade III or IV diabetic wounds/ulcers of the lower extremities:</u>

Diabetic wounds of the lower extremities have been the focus of most wound research in hyperbaric medicine, since the etiology of these wounds is multifactorial, and HBOT can address many of these factors. Based on the body of evidence adjunctive HBOT is recommended for the treatment of diabetic lower extremity wounds that show evidence of deep soft tissue infection, osteomyelitis, or gangrene. HBOT has been shown to reduce the amputation rate in patients with diabetic ulcers as well. Note that HBOT should be used in conjunction with a complete wound healing care plan. As with all chronic wounds, other underlying host factors (e.g., large vessel disease, glycemic control, nutrition, infection,

presence of necrotic tissue, offloading) must be simultaneously addressed in order to have the highest chance of successful healing and functional capacity.

- No standard protocol has been identified for HBOT therapy sessions. Treatment for diabetic wounds of the lower extremities is generally at 2.0 to 2.5 ATA for 90-120 minutes. HBOT is generally performed once daily, 5 days a week for a total of 30 sessions. (Because the goals of HBOT for wound healing include cellular proliferation and angiogenesis, it should not be expected that the wound would be completely healed at the end of the treatment period. There is no published literature that shows improved benefit by providing additional treatment beyond 30 sessions. "The effectiveness of HBOT does not lie solely in the direct healing of lower extremity wounds, but rather in the changes it brings to the periwound area. In addition to the production of growth factors, angiogenesis is stimulated through the production and release of VEGF, which can lead to activation and mobilization of local stem cells. HBOT has been shown to reduce inflammation and apoptosis in the wound allowing for a more hospitable environment for healing to occur.

Idiopathic sudden sensorineural hearing loss ISSHL:

ISSHL is defined as a hearing loss of at least 30 dB occurring within three days over at least three contiguous frequencies. The most common clinical presentation involves an individual experiencing a sudden unilateral hearing loss, tinnitus, a sensation of aural fullness and vertigo. It has been estimated that as many as 65% of cases may resolve spontaneously

- HBOT is considered medically necessary for patients with moderate to profound ISSHL (>/= 41 dB) who present within 14 days of symptom onset. Patients who present with ISSHL should undergo a complete evaluation by an otolaryngologist and audiologist, inclusive of appropriate audiological and imaging studies, to determine the degree and potential etiology of disease.
- Patients determined to have ISSHL and meet the selection criteria may benefit from HBO2. The recommended treatment profile consists of 100% O2 at 2.0 to 2.5 atmospheres absolute for 90 minutes daily for 10 to 20 treatments. The 2.4 ATA treatment pressure is probably most practical, especially for facilities with multiplace chamber operations. Patients with no known contraindications to steroid therapy should also be treated concomitantly with oral corticosteroids. Continued consultation and follow-up with an otolaryngologist is recommended.
- The optimal number of HBOT treatments will vary, depending on the severity and duration of symptomatology and the response to treatment. Utilization review is recommended after 20 treatments.

For Medicare based plan members only, HBOT is a covered as adjunct treatment for refractory actinomycosis. (CMS NCD for Hyperbaric Oxygen Therapy 20.29)

HBOT is covered for the following medical emergencies. HBOT for an emergency medical condition does not require prior authorization.

- Decompression sickness
- Air or gas arterial embolism and symptomatic venous embolism, such as when neurological manifestations or cardiovascular instability exist)
- Acute carbon monoxide poisoning
- Exceptional blood loss (anemia) when blood transfusion is not an option
- Acute carbon monoxide poisoning complicated by cyanide poisoning (after antidote administration has been given)
- Clostridial myositis and myonecrosis (gas gangrene)
- Crush injury, compartment syndrome, and other acute traumatic peripheral ischemias

- Progressive necrotizing infections
- Intracranial abscess
- Partial or full thickness burns covering greater than 20% of total body surface area or with involvement of the hands, face, feet or perineum
- Central retinal artery occlusion

Exclusions

- Topical oxygen therapy (A4575, E0446).
- Off-label use of HBOT for indications for which there is not a recommendation from the Hyperbaric Oxygen Therapy Committee of the Undersea and Hyperbaric Medical Society (UHMS), including but not limited to the treatment of decubitus ulcers, Lyme disease, migraine of any etiology, complex regional pain syndrome, fibromyalgia, cerebral palsy, autistic disorder, or chronic fatigue syndrome, or to prevent mandibular osteoradionecrosis pre and/or post dental extraction, or intraoral implant failure.
- HBOT is not covered for the prevention of mandibular osteoradionecrosis (including but not limited to pre and/or post dental extraction).
- HBOT is not covered to prevent complications or improve survival of intraoral implants in an irradiated field

Codes

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

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Policy History

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