MEDICAL POLICY

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Medical Policy Title	**Hyperbaric Oxygen Therapy (HBOT)**
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Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Topical Hyperbaric Oxygen Therapy

I. Topical hyperbaric oxygen therapy (HBOT) is considered **investigational**.

Systemic Hyperbaric Oxygen Therapy

II. Systemic HBOT in a pressurized chamber is considered **medically appropriate** for the following indications (refer to Policy Guidelines for condition-specific recommendations):

- A. Acute traumatic peripheral ischemia/insufficiency (e.g., crush injury, compartment syndrome, reperfusion injury, and suturing of severed limbs);
- B. Air or gas embolism, acute;
- C. Arterial Inefficiencies: Enhancement of healing in selected wounds of patients who have non-healing wounds of the lower extremities and who have **ALL** the following:
  1. A lower extremity wound due to diabetes;
  2. A wound classified as Wagner grade 3 or higher (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: gangrene of the forefoot);
  3. No measurable signs of healing after 30 days of an adequate course of standard wound therapy; which may include **ANY** of the following:
     - a. assessment of vascular status and correction of any vascular problems in the affected limb if possible;
     - b. optimization of nutritional status;
     - c. optimization of glucose control;
     - d. debridement by any means to remove devitalized tissue;
     - e. maintenance of clean, moist bed of granulation tissue with appropriate moist dressings;
     - f. appropriate off-loading; or
     - g. necessary treatment to resolve any infection that might be present.

D. Carbon monoxide poisoning, acute;

E. Central retinal artery occlusion (CRAO)

F. Cerebral edema, acute;

G. Compromised grafts and flaps (not for primary management of these wounds);

H. Cyanide poisoning, acute;

I. Decompression sickness;

J. Gas/wet gangrene (e.g., clostridial myonecrosis);

K. Idiopathic sudden sensorineural hearing loss (ISSHL)

L. Necrotizing soft tissue infections, based on location and/or organism type and/or particular host immunologic and vascular risk factors causing hypoxia resulting in necrosis;

M. Osteomyelitis, acute, refractory (has not responded to standard medical and surgical management techniques);

N. Osteomyelitis, chronic, refractory (has persisted for at least six (6) weeks or has recurred after appropriate interventions, i.e., surgical debridement and at least one appropriate course of parenteral antibiotics, have been performed);

O. Pre- and post-treatment for patients undergoing dental surgery (non-implant related) of an irradiated jaw;

P. Profound anemia with exceptional blood loss, but only when blood transfusion is impossible or must be delayed;

Q. Radiation necrosis osteoradionecrosis (ORN)/bony necrosis and soft tissue radiation necrosis, (e.g., radiation enteritis, cystitis, proctitis);

R. Refractory mycosis (mucormycosis, actinomycosis, or canidiobolus coronato).

III. Systemic HBOT in a pressurized chamber is considered **investigational** for **ALL** other indications, including, but **not limited to**, the following:

A. Acute ischemic stroke;

B. Amyotrophic Lateral Sclerosis;

C. Arterial peripheral insufficiency, acute; (outside of the other listed medically necessary indications involving arterial insufficiency)

D. Autism spectrum disorders;

E. Bell's palsy;

F. Bone grafts;

G. Breast cancer, locally advanced, as pretreatment for patients undergoing chemotherapy;

H. Brown recluse spider bites;

I. Carbon tetrachloride poisoning, acute;
J. Cardiopulmonary bypass, as pretreatment;
K. Cerebral palsy;
L. Cerebrovascular disease, acute (thrombotic or embolic) or chronic;
M. Chronic, non-healing wounds;
N. Complex regional pain syndrome;
O. COVID-19
P. Uncompromised skin grafts or flaps;
Q. Fibromyalgia syndrome;
R. Fracture healing;
S. Frostbite;
T. Head injury, traumatic (including traumatic brain injury);
U. Tinnitus;
V. Hydrogen sulfide poisoning;
W. Inflammatory bowel disease (Crohn's disease, ulcerative colitis);
X. Interstitial cystitis;
Y. Intra-abdominal and intracranial abscesses;
Z. In vitro fertilization;
AA. Lepromatous leprosy;
BB. Malignant otitis externa;
CC. Meningitis;
DD. Migraine;
EE. Myocardial infarction and acute coronary syndrome (acute myocardial infarction and unstable angina);
FF. Multiple sclerosis;
GG. Muscle soreness, delayed onset;
HH. Prevention of coronary restenosis;
II. Pseudomembranous colitis (antimicrobial agent-induced colitis);
JJ. Pyoderma gangrenosum;
KK. Radiation myelitis;
LL. Radiation therapy, for the purpose of tumor sensitization;

MM. Retinal detachment;

NN. Retinopathy, adjunct to scleral buckling procedures in patients with sickle cell peripheral retinopathy;

OO. Sickle cell crisis and/or hematuria;

PP. Soft tissue injury;

QQ. Spinal cord injury;

RR. Thermal burns, acute.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. 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 following information must be documented, as applicable to the specific medical condition:

   A. Initial assessment and medical history detailing the condition requiring HBOT, and a physical exam. The history should list prior treatments, including antibiotic therapy and surgical interventions.

   B. Current adjunctive treatment that includes type of treatment and its effectiveness.

   C. Established HBOT goals.

   D. HBOT session records describing physical findings and treatment rendered (including ascent time, descent time, total compression time, oxygen dose, pressurization level, documentation of attendance, and a recording of events).

   E. Effect of treatment upon established HBOT goals.

   F. When applicable, advanced diabetic foot ulcers may require photos to avoid overuse of HBOT when the foot is not salvageable. For a Wagner 5 (or Grade D) with complete gangrene of foot, once the heel is necrotic, the patient will likely not respond to HBOT treatments.

II. HBOT treatments of diabetic wounds of the lower extremities should be discontinued when the patient heals, is unable to tolerate treatment, or fails to improve. Documentation must include an assessment of wound healing progress; changes in the wound condition, including the precise wound length, width, and depth measurements; presence of granulation and necrotic tissue; and concurrent measures being addressed relative to wound therapy. Weekly wound measurements should be performed to document progress in wound healing. A steady decrease in wound volume should be noted from week to week.

III. Continued treatment with HBOT is **not covered** if measurable signs of healing have not been demonstrated within any 30-day period of treatment. Most patients should **NOT** require more than 40 treatments. Patients who do not respond to 40 treatments will likely not respond to 60 or 80 or 120 treatments.

IV. Below are specific recommendations on the utilization of HBOT, based upon published, peer-reviewed literature.

Condition	**Pressure (ATA*)**	**Patient Selection Criteria**	**Duration, Frequency, and/or Number of Treatments**	**Utilization review**
Air or Gas embolism, acute	High to low pressure mixed gases	Gases in the vasculature sufficient enough to interfere with the function of an organ and results in ischemia to the affected areas.	Treatment is typically one to two treatments but occasionally may be as many as five to 10; treatment continues until no additional improvement is seen.	After 10 treatments
Anemia, severe	2.0-3.0 ATA	When blood transfusion is impossible or must be delayed.	Treatments of up to three or four hours, three to four times a day. Treatment can continue with taper of time and frequency until red blood cells have been satisfactorily replaced by patient regeneration or the patient can undergo transfusion.	Daily
Arterial Inefficiencies: non-healing *diabetic wounds* of the lower extremities	2.0-3.0 ATA	Wagner grade 3 or higher and failure of standard wound therapy for at least 30 consecutive days.	90-minute treatments, five days per week, are performed in conjunction with continuing standard wound care; may last for 30-40 treatments.	After 40 treatments
Carbon monoxide poisoning, acute	2.5-3.0 ATA	Within six hours of patient removal from the carbon monoxide-contaminated environment.	One treatment; if patient has persistent neurologic dysfunction after the initial treatment further treatment can occur within six to eight	After 5 treatments

Condition	Pressure (ATA*)	Patient Selection Criteria	Duration, Frequency, and/or Number of Treatments	Utilization review
			hours and can be continued once or twice daily until there is no additional improvement in cognitive function.	
Central Retinal Artery Occlusion	2-2.8 ATA	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.	Treat twice daily until clinical plateau plus three days (usually up to 10 days).	After 20 treatments
Compromised Grafts and Flaps	2.0-2.5 ATA	In tissue compromised by irradiation or in other cases where there is decreased perfusion (vascular compromise) or hypoxia, HBOT has been shown to be extremely useful in flap salvage. This indication is not for primary management of wounds for normal, uncompromised skin grafts or flaps.	90-120 minute treatments. It is not unusual to receive treatments twice a day. When the graft or flap appears stable, treatments are reduced to once daily. Should a graft or flap fail, HBOT may be used to prepare the already-compromised recipient site for a new graft or flap. It does not apply to the initial preparation of the body site for a graft.	After 40 treatments
Crush injury	2.0-2.4 ATA	In conjunction with standard therapeutic measures, when loss of function, limb or life is threatened, and tissue	Three 1.5-hour treatments per day for two - three days, then twice a day for two days, and then once daily for two days	After 20 treatments

Condition	Pressure (ATA*)	Patient Selection Criteria	Duration, Frequency, and/or Number of Treatments	Utilization review
		oxygen tension is below 30 mmHg.		
Cyanide poisoning, acute	2.5-3.0 ATA	As an adjunct to infusion of sodium nitrite.	One treatment of 120 minutes.	
Decompression sickness	2.0-5.0 ATA	Gas bubbles in the tissue or blood in volumes sufficient enough to interfere with the function of an organ or cause alteration in sensation.	One treatment of 1.5 to 14 hours; patients who have residual defects after the initial treatment should receive additional treatments until clinical stability is achieved; generally, no more than five to 10 treatments.	After 10 treatments
Gas gangrene (e.g., clostridial myonecrosis)	3.0 ATA	Positive gram-stained smear or culture from tissue fluids, tissue gas visualization on x-ray, severe and sudden pain, skin changes, and edema.	Three 90-minute treatments during the first 24 hours, and then two treatments per day for the next two to five days.	After 10 treatments
Idiopathic Sudden Sensorineural Hearing Loss	2-2.5 ATA	The degree of hearing loss is typically defined as a loss of 30 decibels or more across 3 contiguous frequencies on audiogram. Treatment is recommended either: • combined with steroid therapy within 2 weeks of onset; or • combined with steroid therapy as	Recommend 10-20 sessions.	After 20 treatments

Condition	Pressure (ATA*)	Patient Selection Criteria	Duration, Frequency, and/or Number of Treatments	Utilization review
		salvage within 1 month of onset		
Necrotizing Soft Tissue Infections:	2.0-2.5 ATA	Adjunctive therapy only in patients where morbidity and mortality are expected to be high despite aggressive standard treatment.	Twice daily for 90 to 120 minutes until condition is stabilized, then once daily.	After 30 treatments
Osteomyelitis, chronic, refractory	2.0-2.5 ATA	HBOT should not be used as a primary treatment for osteomyelitis. HBOT should be considered only after surgical debridement and at least one six-week appropriate course of parenteral antibiotics have been performed.	Daily treatment for 90-120 minutes; can be continued for four to six weeks for patients who respond to initial treatment with antibiotics, surgical debridement, and HBOT.	After 30-40 sessions
Osteoradio-necrosis	2.0-2.5 ATA	As adjunctive treatment in the preoperative and postoperative management of the patient.	30 treatments, followed by only minor bony debridement. If response is adequate, an additional 10 treatments can be given. Patients who are not responding are considered stage II; they receive more extensive surgical debridement, then 10 additional treatments. Stage III patients receive 30 treatments, followed by mandibular segmental resection, and then 10 additional treatments.	After 10-30 treatments

Condition	Pressure (ATA*)	Patient Selection Criteria	Duration, Frequency, and/or Number of Treatments	Utilization review
Osteoradio-necrosis, mandibular (i.e., Marx Protocol for ORN and Tooth Extraction)	2.0-2.5 ATA	Evidence of overt fracture or bony resorption. Marx Protocol: Pre-and post-treatment for patients undergoing dental surgery (non-implant-related) of an irradiated jaw.	Initial treatment for stage I patients is 30 treatments. If response is adequate, 10 additional treatments can be provided. Non-responders are considered stage II and receive more extensive surgical debridement, followed by 10 additional treatments. Patients with stage III disease can receive up to 30 treatments, followed by mandibular segmental resection, and then an additional 10 treatments.	After 10-30 treatments
Refractory mycosis (e.g., actinomycosis, mucormycosis)	2.0-2.5 ATA	In conjunction with standard treatment when the disease process is refractory to antibiotics and surgical treatment.	One to two times daily for 90-120 minutes; treatment can continue for up to 40-80 treatments.	After 10-30 treatments

*1 ATA (atmospheres absolute) = pressure of 760 mmHg, 14.7 psi, 760 torr, or 33 ft of seawater.

V. It is recommended that the Centers for Medicare and Medicaid Services (CMS) criteria for coverage be utilized in determining appropriate practitioners to render HBOT. The CMS criteria state:

   A. Qualified non-physician practitioners (NPPs) may supervise HBOT services, if such services are included within their state's scope of practice, if their required supervision or collaborative agreement is with a physician qualified to provide HBOT services, and if the NPP meets the educational requirements identified within the coverage article.

   B. Physicians supervising HBOT should be certified in Undersea and Hyperbaric Medicine by the American Board of Emergency Medicine (ABEM), the American Board of Preventive Medicine (APBM), or the American Osteopathic Conjoint Committee of Undersea and Hyperbaric Medicine (AOCUHM); or must have completed a minimum 40-hour training experience in a program such as one approved by the American College of Hyperbaric Medicine or the

Undersea and Hyperbaric Medical Society.

C. Advanced Cardiac Life Support (ACLS) training and certification of supervising physicians (and NPPs) is required, for provision of HBOT services in physician offices and off-campus hospital sites; and in on-campus, provider-based departments for which provider-response time to the chamber can be expected to exceed five minutes.

D. HBOT services rendered within a hospital outpatient department are considered "incident to" a physician's or qualified NPP's services and require physician supervision. The physician supervision requirement is presumed to be met when services are performed on hospital premises (i.e., certified as part of the hospital and part of the hospital campus); however, in all instances, it is required that the physician be present during the ascent and descent portions of each treatment.

E. In order to satisfy the immediately available criterion, for HBOT performed in an on-campus outpatient hospital or in an off-campus provider-based department, the physician (or qualified NPP) must be present in the office suite or at a location with a maximum of a five-minute response time to the chamber. For HBOT services performed in a physician office, the physician (or qualified NPP) must be present in the office suite.

DESCRIPTION

HBOT is a technique of delivering highly pressurized oxygen to the tissues. Two methods of administration are available.

In systemic, or large chamber, HBOT, the patient is entirely enclosed in a pressure chamber and breathes nearly 100% oxygen intermittently at a pressure greater than one atmosphere (the pressure of O_2 at sea level). This technique relies on the systemic circulation to deliver highly oxygenated blood to the target site, typically a wound. In addition, systemic HBOT can be used to treat systemic illness such as air or gas embolism, carbon monoxide poisoning, clostridial gas gangrene, etc. Treatment may be carried out either in a mono (single person) chamber pressurized with nearly 100% O_2 or in a larger, multi-place (multi-person) chamber pressurized with compressed air, in which case the patient receives pure oxygen by mask, head hood, or endotracheal tube.

Topical HBOT describes a technique of delivering 100% oxygen directly to a wound site at a pressure slightly higher than atmospheric pressure. It is hypothesized that the high concentration of oxygen diffuses directly into the wound to increase the local cellular oxygen tension, which, in turn, promotes wound healing. Topical HBOT devices consist of an appliance to enclose the wound area and a source of O_2; conventional O_2 tanks may be used. The appliances may be disposable and may be used without supervision in the home by well-trained patients. Topical HBOT has been investigated as a treatment for skin ulcerations due to diabetes, venous stasis, post-surgical infection, gangrenous lesion, decubitus ulcers, amputations, skin graft, and frostbite.

SUPPORTIVE LITERATURE

Topical Hyperbaric Oxygen Therapy

de Smet et al. (2017) conducted a systematic review of various oxygen therapies (oxygen dressing therapy, topical oxygen therapy, HBOT, inspired oxygen therapy). Three RCTs evaluating topical oxygen therapy for chronic wound healing were identified. A total of 315 participants with stage II-IV sacral or ischial pressure ulcers (1 RCT) or refractory venous ulcers (2 RCTs) were included in the systematic review. One RCT (n=100) administered treatment for 20 minutes 3 times per day for 12 days to the treatment group and standard care to the control group. The number of patients experiencing complete wound healing, defined as complete epithelialization of the wound without drainage, was 16 in the experimental group and 1 in the control group (p<.001). Two of the RCTs, which had overlapping populations with refractory venous ulcers (n=83 in one and n=132 in the other) administered treatment for 180 minutes 2 times per day for 12 weeks to the treatment group and conventional compression dressing to the control group. In all trials, patients in the treatment group experienced significantly higher proportions of healed ulcers and significantly faster healing times. This systematic review is limited in two of the trials had overlapping populations, so there were not 315 unique patients. There was heterogeneity in the trial populations and treatment regimes. The data are insufficient to draw conclusions about the effect on the net health outcome.

Systemic Hyperbaric Oxygen Therapy

Sharma et al. (2021) conducted a systematic review and meta-analysis of 14 studies (N=768) comparing the effect of HBOT with standard care on diabetic foot ulcers (Table 2). Study authors noted that various modalities can be considered standard care including, but not limited to, debridement, antibiotics, and blood sugar control. However, the specific standard care modality in each included study was not reported. HBOT duration ranged from 45 to 120 minutes (median, 90 minutes). All included studies had methodological limitations, including selection, performance, detection, attrition, and reporting bias. The review found those treated with standard care were less likely to have complete ulcer healing versus HBOT, based on pooled analysis of 11 studies(odds ratio [OR], 0.29; 95% confidence interval [CI], 0.14 to 0.61; I^2=62%). Results were consistent when stratified according to duration of follow up of less than 1 year (7 studies; OR, 0.63; 95% CI, 0.39 to 1.02;I^2=1%) and at 1 year (4 studies; OR, 0.16; 95% CI, 0.03 to 0.82; I^2=83%), although the risk estimate wasn't statistically significant for studies with less than one year follow up. A funnel plot analysis for this outcome was asymmetrical, suggesting publication bias. Risk of major amputation was also significantly lower with HBOT compared to standard care based on pooled analysis of 7 studies (OR, 0.60; 95% CI, 0.39 to 0.92; I^2=24%).There were no clear differences between groups in minor amputation (9 studies; OR, 0.89; 95% CI, 0.71 to1.12) or mortality (3 studies; OR, 0.55; 95% CI, 0.25 to 1.24). Standard care was associated with an increased risk of adverse events compared with HBOT (7 studies; OR, 1.68; 95% CI, 1.07 to 2.65).

A systematic review (Hedetoft 2021) included 31 retrospective cohort studies assessing the effect of adjunctive HBOT for treating necrotizing soft-tissue infections (necrotizing fasciitis, Fournier's gangrene, and gas gangrene). Ten studies assessed to have critical (very high) risk of bias were excluded from meta-analyses. Pooled results from the remaining 21studies found HBOT associated with a reduced risk of in-hospital mortality (OR, 0.44; 95% CI, 0.33 to 0.58;I^2=8%), but the duration of follow-up for mortality was not reported. Results were consistent when studies were stratified according to moderate (5 studies; OR, 0.39; 95% CI, 0.28 to 0.55; I^2=0%) and serious (high) risk of bias (16 studies; OR, 0.51; 95% CI, 0.33 to 0.80; I^2=17%). Publication bias favoring HBOT was

present for this outcome based on funnel plot analysis. For other outcomes, including major amputation and length of hospital stay, there were no statistically significant differences between HBOT use and non-use. Evidence on adjunctive HBOT and the need for surgical debridement was mixed. One study with a low/moderate risk of bias reported a higher number of debridement's with HBOT use versus non-use (mean difference, 1.8; 95% CI,1.15 to 2.45), but the mean difference between HBOT use and non-use in a pooled analysis of 5 studies with methodological flaws was not statistically significant (mean difference, 0.63; 95% CI, -0.49 to 1.75).

Cavaliere et al. (2022) conducted a RCT to compare the effect of HBOT, oral steroids (OS) and a combination of both therapies (HBOT+OS) for treating sudden sensorineural hearing loss (SSNHL). One hundred and seventy-one patients with SSNHL were randomized and included in the study. Participants were evaluated by pure tone audiometry test (PTA) at baseline and 20 days after treatment. After baseline PTA, patients were randomly assigned to each group, HBOT group A, OS-group B, and HBOT+OS-group C. Patients in the HBOT+OS, and HBOT groups improved their auditory function ($p < 0.05$). HBOT was the best choice for treatment when started by seven days from SSNHL onset, while HBOT+OS in case of late treatment. Profound SNHL recovered equally by HBOT, and HBOT+OS ($p < 0.05$). Upsloping SNHL obtained better auditory results by HBOT compared to HBOT+OS ($p < 0.05$). Down sloping and flat SSNHL had the most improvement with HBOT+OS compared to HBOT only ($p < 0.05$). The authors concluded that in both early and late treatment, a combination of HBOT and OS is a valid treatment for SSNHL and had the best results. Limitations include lack of a control group.

Joshua et al. (2022) conducted a systematic review and meta-analysis of RCTs to evaluate the use of HBOT with hearing outcomes in patients with SSNHL and determine if HBOT should be utilized as a single treatment or part of the combination regimen. The study included 3 RCTs, 88 patients who received HBOT in intervention groups and 62 patients who had routine treatment in the control group. The intergroup difference in mean absolute hearing gain (mean difference, 10.3 dB; 95% CI, 6.5-14.1 dB; $I2 = 0\%$) and the odds ratio of hearing recovery (4.3; 95% CI, 1.6-11.7; $I2 = 0\%$) favored HBOT over the control therapy. The authors suggest that HBOT as part of a combination treatment regimen should be considered for patients with SSNHL. Limitations include small sample sizes of studies, and the secondary outcome (adverse effect of treatment) could not be assessed. The authors recommend further studies to assess the adverse effects of treatment and to determine the optimal HBOT protocol.

Rhee et al. (2018) performed a systematic review and meta-analysis through February 2018 for patients comparing HBOT plus medical therapy (MT) with MT alone for ISSNHL treatment. Randomized clinical trials and nonrandomized studies were included. The main outcomes considered were complete hearing recovery, any hearing recovery, and absolute hearing gain. Nineteen studies (3 randomized and 16 nonrandomized) with a total of 2401 patients (mean age, 45.4 years; 55.3% female) were included. In the HBOT+MT group, rates of complete hearing recovery and any hearing recovery were 264/897 (29.4%) and 621/919 (67.6%),respectively, and in the MT alone group were 241/1167 (20.7%) and 585/1194 (49.0%), respectively. Pooled HBOT+MT also showed favorable pooled results from random-effects models for both complete hearing recovery (OR, 1.61; 95% CI, 1.05 to 2.44) and any hearing recovery (OR, 1.43; 95% CI, 1.20 to 1.67). The study was limited by the following: (1) differences in clinical and methodological characteristics of selected studies, (2)

considerable heterogeneity, (3) the possibility of measured or unmeasured confounder effects, and(4) difficulty in evaluating the benefit of treatment due to a substantial proportion of patients experiencing spontaneous recovery.

Včeva et al. (2022) published a retrospective study that included a total of 59 patients (31 males and 28 females, median age 56 years) treated for ISSNHL with HBOT in the period from January 2015 to the end of December 2019. Patients were offered various treatments, and the patients with sudden sensorineural hearing loss of idiopathic cause included in this study were those who refused corticosteroid therapy. The median time from the onset of symptoms to treatment was three days. A pure-tone audiogram was recorded in all patients during the first visit to the otorhinolaryngologist and after completion of the HBOT course. Following HBOT (90 min at 203 kPa daily for 20 days), hearing loss was significantly reduced with the median loss across all frequencies falling from 81.2 dB (IQR 70.0−95.0) to 58.1 dB (IQR 47.5−77.5) ($P < 0.001$). The difference in the median value of hearing loss before and after HBOT across all patients was 22.5 dB (IQR 12.5–33.75). Significantly lower hearing thresholds were observed at 500, 1,000, 2,000 and 4,000 Hz after treatment, with the largest difference at 1,000 Hz. There were four patients who started HBOT greater than 14 days from the onset of symptoms. The median value of hearing recovery (difference in hearing thresholds before and after HBOT) was 17.5 dB (IQR 4.1–38.4), and the median hearing threshold after HBOT was 54.3 dB (IQR 51.8–68.1) for these 'delayed' patients. There was no significant difference in recovery (difference in hearing threshold before and after HBOT) between patients who started therapy within seven days, 7–14 days, or > 14 days from the onset of symptoms ($P = 0.39$). There was no association between treatment initiation time and recovery. The principal limitation of this study is the lack of a comparator group primarily treated with corticosteroids that would allow comparison of outcomes with those obtained using HBOT. The study is also small and retrospective in design. The authors concluded the study showed HBOT is a legitimate choice as the primary treatment for ISSNHL, especially if it is readily accessible, and if there are contraindications for corticosteroid therapy.

Wu et al. (2018) conducted a meta-analysis to determine the effectiveness of oxygen therapy in retinal artery occlusion patients. The primary endpoint was visual acuity (VA). Seven RCTs met inclusion criteria. Patients who received oxygen therapy exhibited probability of visual improvement about 5.61 times compared with the control group who did not receive oxygen therapy. No statistically significant difference was observed between oxygen inhalation methods, combined therapy, or RAO type. Conversely, 100% oxygen and hyperbaric oxygen significantly improved VA in RAO patients. Better effect was showed in period within three months and the most effective treatment length was over nine hours. The authors concluded that oxygen therapy had beneficial effects in improving VA in RAO patients, especially when treated with 100% hyperbaric oxygen for over nine hours.

Boyoung M et al. (2025) published a retrospective clinical cohort study to describe the outcomes of HBOT for patients with central retinal artery occlusion (CRAO) at a single tertiary care center. Medical records of all patients diagnosed with CRAO who received HBOT at Mayo Clinic in Rochester, Minnesota from January 1, 2009 to December 31, 2020 were reviewed to confirm diagnosis, time from onset to presentation, exam findings, treatments, and follow-up data. Main outcome measures included final visual acuity (VA) and number of lines of improvement. There were 41 patients

diagnosed with CRAO who received HBOT during the 12-year study period. Median time from symptom onset to HBOT treatment was 9.5 h (interquartile range [IQR] 6.5, 14.0 h), and patients received a median of 4 HBOT sessions (IQR 2.5, 6.0 sessions). There were 20 patients who received HBOT within 9 h, 14 (70%) of which had clinically meaningful improvement in VA of ≥0.3 logMAR. In comparison, of the 21 patients treated after 9 h, 6 (28.6%) had VA improvement of ≥0.3 logMAR (P = .008). For all patients, the median logMAR VA at presentation was 2.00 (IQR 1.70, 2.30) and the median logMAR VA at follow-up was 1.94 (IQR 1.00, 2.00) (P < .001), with median lines of improvement of 3.0 (IQR 0.0, 7.0). For patients treated within 9 h, the median logMAR VA at presentation was 2.00 (IQR 1.93, 2.30) and the median logMAR VA at follow-up was 1.70 (IQR 0.54, 2.00). Patients treated within 9 h had statistically significant greater median lines of VA improvement than cases that were treated after >9 h from symptom onset at 5.9 (IQR 3.0, 10.0) and 0.0 (IQR 0.0, 3.0), respectively (P < .001). There was no difference in VA recovery associated with specific retinal exam findings such as cherry-red spot (P = .22) and cilioretinal artery perfusion (P = .36) compared to patients without those findings. Limitations of the study include the retrospective design and the small cohort of patients. There was a statistically significant improvement in VA after HBOT treatment in CRAO patients among patients that received early HBOT, with patients receiving the most benefit when receiving treatment within 9 h.

Maldonado et al. (2024) published a retrospective study to report the visual acuity outcomes in all patients with CRAO and symptoms lasting for less than 24 hours who were prescribed HBOT in the Hyperbaric Medicine Unit of a Portuguese hospital from March 2009 to February 2023. All patients were subjected to 90-minute HBOT sessions with 100% oxygen at 2.4 ATA. The primary outcome was VA change (dif-logMAR) before and after treatment. A clinically significant visual improvement was defined as a dif-logMAR≥0.3. A total of 114 patients were included in this study; 68% (n=77) were male, with a mean age of 69 years, and were subjected to a median number of seven HBOT sessions. No serious adverse effects from HBOT were reported. The mean time delay from symptoms to treatment was 12 hours, and best-corrected visual acuity (BCVA) at baseline was counting fingers or worse in 84% (n=96) of the patients. A dif-logMAR≥0.3 occurred in 46% (n=52) of the patients, and 58% (n=66) reported subjective VA improvement after the treatment. A significant improvement between BCVA before HBOT (2.12±0.74) and after HBOT (1.67±0.74) was observed. The VA outcome was found to be related to the total number of sessions, age, obesity, supplementary treatments, and cherry-red spot (CRS) at presentation. There were no significant effects of the time delay from symptoms to treatment in the explanation of the VA outcome. Limitations of the study included the retrospective design and absence of a control group for ethical reasons. The authors concluded HBOT appears to be safe and has a beneficial effect on VA outcomes in patients with non-arteritic CRAO, particularly depending on the number of sessions. Patient factors such as age, obesity, and the presence of CRSs also appear to influence the VA outcome.

Bagli BS et al. (2018) aimed to investigate efficacy of HBO2 treatment in CRAO patients that were referred to their Hyperbaric Oxygen Treatment Unit. Patient demographics, their systemic diseases, best-corrected visual acuity (BCVA) and the time of visual loss were recorded. Oral acetazolamide and topical beta blocker treatments as well as HBO2 treatments were administered to patients as soon as possible. Patients received 20 treatments as standard. Visual acuity was examined and recorded following each HBO2 treatment administration. 10 eyes (five right, five left) of 10 patients)

were included in the study. While average visual acuity was LogMAR 3 before the treatment, it was measured as LogMAR 1.8 on average after treatment (P ⟨ 0.05). None of the patients were observed to have neovascular glaucoma. The authors concluded their study showed HBO2 treatment is an efficacious method with few side effects and can be used in the treatment of CRAO patients. During acute and subacute periods, a certain number of HBO2 treatment sessions may be beneficial. Stopping treatments before eight completed HBO2 sessions for a patient who did not show improvement until that time may miss a patient who would have benefited from HBO2 treatment.

Kim YS et al. (2020) published a registry-based observational study which included adult patients who presented to the emergency department or ophthalmology outpatient department within 24 hours of the onset of CRAO symptoms. Data of patients from October 2016 to February 2019 were analyzed. The patients were categorized into two groups according to the use of adjunctive HBO2: no HBO2 and HBO2. During the study period, 34 consecutive patients were enrolled, of which 19 were included in the study. In the total cohort, 10 patients (52.6%) were treated with adjunctive HBO2. There were no statistically significant differences in terms of age, sex, comorbidities, duration from symptoms onset to hospital visit, presence of the cilioretinal artery, and use of anterior chamber paracentesis between the two groups. The HBO2 group showed significantly higher change in best-corrected visual acuity than the no HBO2 group (p=0.043). The authors concluded the study showed patients with CRAO in the HBO2 group showed significantly greater visual improvement than those in the no-HBO2 group.

A 2016 Cochrane review by Xiong et al. identified one randomized, controlled trial (RCT) evaluating systemic HBOT for people with autism spectrum disorder who met reviewers' eligibility criteria, and that trial did not find significantly improved outcomes with HBOT versus sham. The authors concluded that there is no evidence that HBOT improves core symptoms and associated symptoms of ASD, adding that it is important to note that adverse effects (minor-grade ear barotrauma events) can occur. Given the absence of evidence of effectiveness, the limited biological plausibility, and possible adverse effects, the need for future RCTs of HBOT must be carefully considered.

Published clinical trials have not provided evidence to support the efficacy and safety of HBOT over current treatment options for the indications listed as investigational in this policy.

PROFESSIONAL GUIDELINE(S)

The Undersea and Hyperbaric Medical Society (UHMS) (2023) published recommended indications for systemic hyperbaric oxygen therapy which include the following:

- air or gas embolism
- arterial insufficiencies
    - central retinal artery occlusions
    - selected problem wounds-diabetic ulcers (microvascular insufficiency)
- carbon monoxide poisoning/ carbon monoxide poisoning complicated by cyanide poisoning
- clostridial myositis and myonecrosis (gas gangrene)

- crush injury, compartment syndrome, and other acute traumatic ischemias
- decompression sickness
- severe anemia
- intracranial abscesses
- necrotizing infections
- osteomyelitis (refractory)
- delayed radiation injury (soft tissue and bony necrosis)
- compromised skin grafts and flaps
- acute thermal burn injury
- idiopathic sudden sensorineural hearing loss
- Avascular necrosis (aseptic osteonecrosis)

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

In December 2009, the Undersea and Hyperbaric Medical Society issued a position paper stating that the society does not recommend routine treatment of autism with HBOT, as there is very little evidence to support an effect of pressure alone or that oxygen has differing effects whether given by increasing ambient pressure or increasing the inspired fraction.

In 2019, the American Academy of Otolaryngology-Head and Neck Surgery updated clinical guidelines on the treatment of sudden sensorineural hearing loss (SSNHL) (Chandrasekhar 2019).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.

In 2025, The American Academy of Ophthalmology (AAO) published a Preferred Practice Pattern for Retinal and Ophthalmic Artery Occlusions (Kovach 2025). They state the use of hyperbaric oxygen therapy (100% oxygen over 9 hours) has demonstrated efficacy over observation alone in several small retrospective studies (Wu 2018, Chiabo 2024). However, a Cochrane review concluded that evidence is uncertain regarding interventions and well-designed randomized controlled trials are needed (Lin 2023).

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.

In 2019 the American Heart Association and American Stroke Association updated the guidelines for early management of acute ischemic stroke (Powers 2019). 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."

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 (Hingorani 2016) . 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 (grade1B). 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).

REGULATORY STATUS

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. Last updated in 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.

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. Patients receiving HBOT are at risk of suffering an injury that can be mild (such as sinus pain, ear pressure, painful joints) or serious (such as paralysis, air embolism). Since hyper baric chambers are oxygen rich environments, there is also a risk of fire.

The FDA states the safety and effectiveness of HBOT has not been established for these diseases and conditions, including:

- AIDS/HIV
- Alzheimer's Disease
- Asthma
- Bell's Palsy
- Brain Injury
- Cerebral Palsy
- Depression

- Heart Disease
- Hepatitis
- Migraine
- Multiple Sclerosis
- Parkinson's Disease
- Spinal Cord Injury
- Sport's Injury
- Stroke

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session

HCPCS Codes

Code	Description
A4575 (E/I)	Topical hyperbaric oxygen chamber, disposable
E0446 (E/I)	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval

ICD10 Codes

Code	Description
A18.01	Tuberculosis of spine
A18.03	Tuberculosis of other bones
A42.0-A42.2	Actinomycosis (code range)

Code	Description
A42.81-A42.89	Other forms of actinomycosis (code range)
A42.9	Actinomycosis, unspecified
A43.0-A43.9	Nocardiosis (code range)
A48.0	Gas gangrene
A50.01-A50.09	Early congenital syphilis, symptomatic (code range)
A52.77	Syphilis of bone and joint
B36.0-B36.9	Other superficial mycoses (code range)
B47.1	Actinomycetoma
B47.9	Mycetoma, unspecified
B48.3	Geotrichosis
B48.8	Other specified mycoses
B49	Unspecified mycosis
D62	Acute posthemorrhagic anemia
E08.52	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy with gangrene
E09.52	Drug or chemical induced diabetes mellitus with diabetic peripheral angiopathy with gangrene
E10.52	Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E10.618-E10.69	Type 1 diabetes mellitus with other specified complications (code range)
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E11.618-E11.69	Type 2 diabetes mellitus with other specified complication
E13.52-E13.69	Other specified diabetes mellitus (code range)
G93.6	Cerebral edema

Code	Description
H05.021-H05.029	Osteomyelitis of orbit (code range)
H90.3	Sensorineural hearing loss, bilateral
H90.5	Unspecified sensorineural hearing loss
H90.A2-H90.A22	Sensorineural hearing loss, unilateral, with restricted hearing on the contralateral side (code range)
H91.2-H91.23	Sudden idiopathic hearing loss (code range)
H34.1-H34.13	Central retinal artery occlusion (code range)
I70.361-I70.369	Atherosclerosis of bypass graft(s) of the extremities with gangrene (code range)
I70.461-I70.469	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene (code range)
I73.01	Raynaud's syndrome with gangrene
I96	Gangrene, not elsewhere classified
K12.2	Cellulitis and abscess of mouth
L02.01-L02.93	Cutaneous abscess, furuncle, and carbuncle (code range)
L03.111-L03.119	Cellulitis of other parts of limb (code range)
L03.121-L03.129	Acute lymphangitis (code range)
L03.211-L03.91	Cellulitis and acute lymphangitis (code range)
L08.1	Erythrasma
L59.9	Disorder of the skin and subcutaneous tissue related to radiation, unspecified
L98.3	Eosinophilic cellulitis (Wells)
M27.2	Inflammatory conditions of jaws
M27.8	Other specified diseases of jaws

Code	Description
M46.20-M46.28	Osteomyelitis of vertebra (code range)
M46.30-M46.39	Infection of intervertebral disc (pyogenic) (code range)
M86.00-M86.09	Acute hematogenous osteomyelitis (code range)
M86.10-M86.19	Other acute osteomyelitis (code range)
M86.20-M86.29	Subacute osteomyelitis (code range)
M86.30-M86.69	Chronic osteomyelitis (code range)
M86.8x0-M86.9	Other and unspecified osteomyelitis (code range)
M90.80-M90.89	Osteopathy in diseases classified elsewhere (code range)
P11.0	Cerebral edema due to birth injury
S06.1x0A-S06.1x9A	Traumatic cerebral edema (code range)
S07.0xxA, S17.9xxA,	Crushing injury (code range)
T57.3x1A-T57.3x4A	Toxic effect of hydrogen cyanide (code range)
T58.01xA-T58.94xA	Toxic effect of carbon monoxide (code range)
T65.0x1A-T65.0x4A	Toxic effect of cyanides (code range)
T66.xxxA-T66.xxxS	Radiation sickness, unspecified (code range)
T70.3xxA-T70.3xxS	Caisson disease (decompression sickness) (code range)
T79.0xxA-T79.0xxS	Air embolism (traumatic) (code range)

Code	Description
T86.820-T86.822	Complications of skin graft (allograft) (autograft) (code range)
T86.828-T86.829	Other and unspecified complications of skin graft (allograft) (autograft) (code range)

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SEARCH TERMS

HBOT, Systemic hyperbaric oxygen therapy, Topical hyperbaric oxygen pressurization, Topical hyperbaric oxygen therapy, Topical oxygen wound therapy, TOWT.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Hyperbaric Oxygen Therapy (NCD 20.29) [accessed 2025 Apr 17]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

11/19/99, 04/17/02, 04/24/03, 05/19/04, 07/21/05, 09/21/06, 07/19/07, 06/19/08, 09/18/08, 09/17/09, 02/17/11, 04/19/12, 03/21/13, 03/20/14, 03/19/15, 03/17/16, 04/20/17, 05/17/18, 05/16/19, 05/21/20, 05/20/21, 05/19/22, 05/18/23, 05/16/24, 06/26/25

Date	Summary of Changes
06/26/25	• Annual update, ISSHL and CRAO added to medically necessary indications in policy statement II, removed from investigation indications in policy statement III.
01/01/25	• Summary of changes tracking implemented.

11/19/99	• Original effective date