BlueCross BlueShield Federal Employee Program.

FEP 2.01.04 Hyperbaric Oxygen Therapy

Effective Date: April 15, 2018

Related Policies: None

Hyperbaric Oxygen Therapy

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 has been investigated for various conditions that have potential to respond to increased oxygen delivery to tissue.

FDA REGULATORY STATUS

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.

POLICY STATEMENT

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

- nonhealing diabetic wounds of the lower extremities in patients who meet the following 3 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 section); and
  c. Patient has no measurable signs of healing after 30 days of an adequate course of standard wound therapy;
- acute traumatic ischemia (eg, crush injuries, reperfusion injury, compartment syndrome);
- decompression sickness;
- gas embolism, acute;
- cyanide poisoning, acute;
- acute carbon monoxide poisoning;
- soft-tissue radiation necrosis (eg, radiation enteritis, cystitis, proctitis) and osteoradionecrosis;
- pre- and posttreatment for patients undergoing dental surgery (non-implant-related) of an irradiated jaw;
- gas gangrene (ie, 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 **not medically necessary** 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 (eg, multiple sclerosis, amyotrophic lateral sclerosis);
- retinal artery insufficiency, acute;
- retinopathy, adjunct to scleral buckling procedures in patients 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 (ie, posttraumatic stress disorder, generalized anxiety disorder or depression).

POLICY GUIDELINES

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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

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 2 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.

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.

For individuals with acute thermal burns who receive systemic HBOT, the evidence includes a systematic review of 2 RCTs. Relevant outcomes are overall survival, symptoms, and change in disease status. Only 2 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 4 RCTs identified (eg, 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 3-month follow-up; however, there were no significant benefits of HBOT for most health outcomes compared with standard care in the long-term (6 months to 2 years). The evidence is insufficient to determine 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 patients 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 6 RCTs. There were 2 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 3-6 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 2 months than with delayed treatment. However, the trial had a number of methodologic limitations (eg, 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.

For individuals with idiopathic sudden sensorineural hearing loss who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, change in disease status, and functional outcomes. A Cochrane review with pooled analysis of 2 RCTs did not find a statistically significant difference in outcomes between the HBOT and the control groups in hearing for all frequencies at a level greater tha 50%, but did find a statistical difference at a level greater than 25%. An RCT published after the review reported no differences in hearing between groups at 4 different frequencies. The RCTs had methodologic limitations. 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 (eg, 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 2 RCTs and an observational study. Relevant outcomes are symptoms and functional outcomes. One RCT was stopped early due to futility, and the other did not find significantly better outcomes with HBOT than with a sham intervention. The observational study focused on sleep disorders in children with cerebral palsy and reported improvements with the HBOT treatment. The evidence is insufficient to determine 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 2 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 (ie, 6-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 3 of the 11 trials. Meta-analysis of these 3 RCTs found significantly greater relief of migraine symptoms with HBOT than with a comparator intervention within 45 minutes of treatment. Longer term data are needed. The evidence is insufficient to determine 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 (ie, 6-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 2 RCTs were identified, and both reported positive effects of HBOT on tender points and pain. However, the trials had relatively small samples and methodologic limitations (eg, 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 (eg, 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Diabetic Foot Conditions

Undersea and Hyperbaric Medical Society

In 2015, the Undersea and Hyperbaric Medical Society (UHMS) published guidelines on the use of hyperbaric oxygen therapy (HBOT) for treating diabetic foot ulcers.[61] This guideline is scheduled for a revision in 2018. 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.

Infectious Disease Society of America

In 2012, the Infectious Disease Society of America published guidelines on the diagnosis and treatment of diabetic foot infections.[62] The guidelines stated that "for selected diabetic foot wounds that are slow to heal, clinicians might consider using hyperbaric oxygen therapy (strength of evidence: strong; quality of evidence: moderate)."

Society of Vascular Surgery et al

In 2016, the Society of Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine published guidelines on the management of the diabetic foot.[63] According to the guidelines, for diabetic foot ulcers that fail to demonstrate improvement (>50% wound area reduction) after a minimum of 4 weeks of standard wound therapy, adjunctive therapy such as HBOT is recommended (grade 1B). Also, for diabetic foot ulcers with adequate perfusion that fail to respond to 4 to 6 weeks of conservative management, HBOT is suggested (grade 2B).

Other Conditions

Undersea and Hyperbaric Medical Society

The 2014 UHMS hyperbaric oxygen therapy indications committee report included the following indications as recommended[64]:

1. Air or Gas Embolism
2. Carbon Monoxide Poisoning and carbon monoxide 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
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.

American Academy of Otolaryngology–Head and Neck Surgery

In 2012, the American Academy of Otolaryngology–Head and Neck Surgery published clinical guidelines on treatment of sudden hearing loss.[68] The guidelines included a statement that HBOT may be considered a treatment option for patients who present within 3 months of a diagnosis of idiopathic sudden sensorineural hearing loss (ISSNHL): "Although HBOT is not widely available in the United States and is not recognized by many U.S. clinicians as an intervention for ISSNHL, the panel felt that the level of evidence for hearing improvement, albeit modest and imprecise, was sufficient to promote greater awareness of HBOT as an intervention for ISSNHL" (grade B recommendation, based on systematic review of RCTs with methodological limitations).

Tenth European Consensus Conference on Hyperbaric Medicine

The 10th European Consensus Conference on Hyperbaric Medicine (ECHM) convened in April 2016 to update HBOT indication recommendations.[69] Evidence was assessed using a modified GRADE system with the DELPHI system for consensus evaluation. Table 1 presents the updated recommendations:

Table 1 Recommendations on Hyperbaric Medicine

Condition	SOR	LOE
Carbon monoxide poisoning	Strong	Moderate
Open fractures with crush injury	Strong	Moderate
Prevention of osteoradionecrosis	Strong	Moderate
Osteoradionecrosis (mandible)	Strong	Moderate
Soft tissue radionecrosis (cystitis, proctitis)	Strong	Moderate
Decompression illness	Strong	Low
Gas embolism	Strong	Low
Anaerobic or mixed bacterial infection	Strong	Low
Sudden deafness	Strong	Moderate
Diabetic foot lesions	Weak	Moderate
Femoral head necrosis	Weak	Moderate
Compromised skin grafts and musculocutaneous flaps	Weak	Low
Central retinal artery occlusion	Weak	Low
Crush injury without fracture	Weak	Low
Osteoradionecrosis (other than mandible)	Weak	Low
Radio-induced lesions of soft tissues	Weak	Low
Radio-induced lesions of soft tissues (preventive)	Weak	Low
Ischemic ulcers	Weak	Low
Refractory chronic osteomyelitis	Weak	Low
Burns, second degree, >20% body surface area	Weak	Low
Pneumatosis cystoides intestinalis	Weak	Low
Neuroblastoma, stage IV	Weak	Low
Brain injury in highly selected patients	Neutral	Low
Radio-induced lesions of larynx	Neutral	Low
Radio-induced lesions of central nervous system	Neutral	Low
Post-vascular procedure reperfusion syndrome	Neutral	Low
Limb replantation	Neutral	Low
Selected non-healing wounds, secondary to systemic process	Neutral	Low

Sickle cell disease	Neutral	Low
Interstitial cystitis	Neutral	Low

Adapted from Mathieu et al (2017).[69]
LOE: level of evidence; SOR: strength of recommendation.

Following the publication of the European Consensus Conference on Hyperbaric Medicine update, a letter to the editor requested details on the modified GRADE system and commented on the lack of a reference list in the update publication.

Dana Farber/Brigham and Women's Cancer Center

In 2017, the Dana Farber/Brigham and Women's Cancer Center conducted a systematic review of the evidence for HBOT for the prevention and management of osteoradionecrosis (ORN) of the jaw.[70] The literature search, conducted in January 2016, identified 3 studies on the prevention of ORN (1 RCT, 2 retrospective cohorts) and 4 studies on the management of ORN (1 RCT, 3 retrospective cohorts). Based on results from these studies, the Center "does not recommend the routine use of HBO for the prevention or management of ORN. Adjunctive HBO may be considered for use on a case-by-case basis in patients considered to be at exceptionally high risk who have failed conservative therapy and subsequent surgical resection."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

In 2003, the Centers for Medicare & Medicaid added Medicare coverage of HBOT for diabetic wounds of the lower extremities meeting certain criteria. As of the current coverage statement, Medicare coverage is provided for HBOT administered in a chamber for the following conditions[71]:

1. "Acute carbon monoxide intoxication,
2. Decompression illness,
3. Gas embolism,
4. Gas gangrene,
5. Acute traumatic peripheral ischemia. HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened.
6. Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened.
7. Progressive necrotizing infections (necrotizing fasciitis),
8. Acute peripheral arterial insufficiency,
9. Preparation and preservation of compromised skin grafts (not for primary management of wounds),
10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management,
11. Osteoradionecrosis as an adjunct to conventional treatment,
12. Soft tissue radionecrosis as an adjunct to conventional treatment,
13. Cyanide poisoning,
14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment,
15. Diabetic wounds of the lower extremities in patients who meet the following three criteria:
    a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
    b. Patient has a wound classified as Wagner grade III or higher; and
    c. Patient has failed an adequate course of standard wound therapy.

The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30–days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes: assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment."

REFERENCES

1. Sadri RA, Cooper JS. Hyperbaric, complications. *NCBI Bookshelf* 2017; https://www.ncbi.nlm.nih.gov/books/NBK459191/. Accessed November 21, 2017.
2. Federal Food and Drug Administration. Hyperbaric Oxygen Therapy: Don't Be Misled. 2013; http://www.fda.gov/forconsumers/consumerupdates/ucm364687.htm. Accessed November 21, 2017.
3. de Smet GHJ, Kroese LF, Menon AG, et al. Oxygen therapies and their effects on wound healing. *Wound Repair Regen.* Aug 2017;25(4):591-608. PMID 28783878
4. Leslie CA, Sapico FL, Ginunas VJ, et al. Randomized controlled trial of topical hyperbaric oxygen for treatment of diabetic foot ulcers. *Diabetes Care.* Feb 1988;11(2):111-115. PMID 3289861
5. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Hyperbaric oxygen therapy for wound healing. Part I. *TEC Assessments.* 1999;Volume 14:Tab 13.
6. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Hyperbaric oxygen therapy for wound healing. Part II. *TEC Assessments.* 1999;Volume 14:Tab 15.
7. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Hyperbaric oxygen therapy for wound healing. Part III. *TEC Assessments.* 1999;Volume 14:Tab 16.
8. Kranke P, Bennett MH, Martyn-St James M, et al. Hyperbaric oxygen therapy for chronic wounds. *Cochrane Database Syst Rev.* Jun 24 2015(6):CD004123. PMID 26106870
9. Elraiyah T, Tsapas A, Prutsky G, et al. A systematic review and meta-analysis of adjunctive therapies in diabetic foot ulcers. *J Vasc Surg.* Feb 2016;63(2 Suppl):46S-58S e41-42. PMID 26804368
10. Buckley NA, Juurlink DN, Isbister G, et al. Hyperbaric oxygen for carbon monoxide poisoning. *Cochrane Database Syst Rev.* Apr 13 2011(4):CD002041. PMID 21491385
11. Bennett MH, Feldmeier J, Hampson NB, et al. Hyperbaric oxygen therapy for late radiation tissue injury. *Cochrane Database Syst Rev.* Apr 28 2016;4:CD005005. PMID 27123955
12. Borab Z, Mirmanesh MD, Gantz M, et al. Systematic review of hyperbaric oxygen therapy for the treatment of radiation-induced skin necrosis. *J Plast Reconstr Aesthet Surg.* Apr 2017;70(4):529-538. PMID 28081957
13. Ravi P, Vaishnavi D, Gnanam A, et al. The role of hyperbaric oxygen therapy in the prevention and management of radiation-induced complications of the head and neck - a systematic review of literature. *J Stomatol Oral Maxillofac Surg.* Dec 2017;118(6):359-362. PMID 28838774
14. Maynor ML, Moon RE, Camporesi EM, et al. Chronic osteomyelitis of the tibia: treatment with hyperbaric oxygen and autogenous microsurgical muscle transplantation. *J South Orthop Assoc.* Spring 1998;7(1):43-57. PMID 9570731
15. Davis JC, Heckman JD, DeLee JC, et al. Chronic non-hematogenous osteomyelitis treated with adjuvant hyperbaric oxygen. *J Bone Joint Surg Am.* Oct 1986;68(8):1210-1217. PMID 3771602
16. Chen CE, Ko JY, Fu TH, et al. Results of chronic osteomyelitis of the femur treated with hyperbaric oxygen: a preliminary report. *Chang Gung Med J.* Feb 2004;27(2):91-97. PMID 15095953
17. Chen CE, Shih ST, Fu TH, et al. Hyperbaric oxygen therapy in the treatment of chronic refractory osteomyelitis: a preliminary report. *Chang Gung Med J.* Feb 2003;26(2):114-121. PMID 12718388
18. Chen CY, Lee SS, Chan YS, et al. Chronic refractory tibia osteomyelitis treated with adjuvent hyperbaric oxygen: a preliminary report. *Changgeng Yi Xue Za Zhi.* Jun 1998;21(2):165-171. PMID 9729650
19. Villanueva E, Bennett MH, Wasiak J, et al. Hyperbaric oxygen therapy for thermal burns. *Cochrane Database Syst Rev.* Jul 2004(3):CD004727. PMID 15266540
20. Eskes A, Vermeulen H, Lucas C, et al. Hyperbaric oxygen therapy for treating acute surgical and traumatic wounds. *Cochrane Database Syst Rev.* Dec 16 2013;12(12):CD008059. PMID 24343585

21. Dauwe PB, Pulikkottil BJ, Lavery L, et al. Does hyperbaric oxygen therapy work in facilitating acute wound healing: a systematic review. *Plast Reconstr Surg.* Feb 2014;133(2):208e-215e. PMID 24469192
22. Freiberger JJ, Padilla-Burgos R, McGraw T, et al. What is the role of hyperbaric oxygen in the management of bisphosphonate-related osteonecrosis of the jaw: a randomized controlled trial of hyperbaric oxygen as an adjunct to surgery and antibiotics. *J Oral Maxillofac Surg.* Jul 2012;70(7):1573-1583. PMID 22698292
23. Levett D, Bennett MH, Millar I. Adjunctive hyperbaric oxygen for necrotizing fasciitis. *Cochrane Database Syst Rev.* Jan 15 2015;1:CD007937. PMID 25879088
24. Jallali N, Withey S, Butler PE. Hyperbaric oxygen as adjuvant therapy in the management of necrotizing fasciitis. *Am J Surg.* Apr 2005;189(4):462-466. PMID 15820462
25. George ME, Rueth NM, Skarda DE, et al. Hyperbaric oxygen does not improve outcome in patients with necrotizing soft tissue infection. *Surg Infect (Larchmt).* Feb 2009;10(1):21-28. PMID 18991520
26. Bennett MH, Lehm JP, Jepson N. Hyperbaric oxygen therapy for acute coronary syndrome. *Cochrane Database Syst Rev.* Jul 23 2015(7):CD004818. PMID 26202854
27. Bennett MH, Weibel S, Wasiak J, et al. Hyperbaric oxygen therapy for acute ischaemic stroke. *Cochrane Database Syst Rev.* Nov 12 2014;11(11):CD004954. PMID 25387992
28. Efrati S, Fishlev G, Bechor Y, et al. Hyperbaric oxygen induces late neuroplasticity in post stroke patients--randomized, prospective trial. *PLoS One.* Jan 2013;8(1):e53716. PMID 23335971
29. Holland NJ, Bernstein JM, Hamilton JW. Hyperbaric oxygen therapy for Bell's palsy. *Cochrane Database Syst Rev.* Feb 15 2012;2(2):CD007288. PMID 22336830
30. Wang F, Wang Y, Sun T, et al. Hyperbaric oxygen therapy for the treatment of traumatic brain injury: a meta-analysis. *Neurol Sci.* May 2016;37(5):693-701. PMID 26746238
31. Crawford C, Teo L, Yang E, et al. Is hyperbaric oxygen therapy effective for traumatic brain injury? a rapid evidence assessment of the literature and recommendations for the field. *J Head Trauma Rehabil.* May/Jun 2017;32(3):E27-E37. PMID 27603765
32. Bennett MH, Trytko B, Jonker B. Hyperbaric oxygen therapy for the adjunctive treatment of traumatic brain injury. *Cochrane Database Syst Rev.* Dec 12 2012;12:CD004609. PMID 23235612
33. Wolf G, Cifu D, Baugh L, et al. The effect of hyperbaric oxygen on symptoms after mild traumatic brain injury. *J Neurotrauma.* Nov 20 2012;29(17):2606-2612. PMID 23031217
34. Cifu DX, Walker WC, West SL, et al. Hyperbaric oxygen for blast-related postconcussion syndrome: three-month outcomes. *Ann Neurol.* Feb 2014;75(2):277-286. PMID 24255008
35. Miller RS, Weaver LK, Bahraini N, et al. Effects of hyperbaric oxygen on symptoms and quality of life among service members with persistent postconcussion symptoms: a randomized clinical trial. *JAMA Intern Med.* Jan 2015;175(1):43-52. PMID 25401463
36. Marois P, Mukherjee A, Ballaz L. Hyperbaric oxygen treatment for persistent postconcussion symptoms-a placebo effect? *JAMA Intern Med.* Jul 1 2015;175(7):1239-1240. PMID 26146912
37. Dulai PS, Gleeson MW, Taylor D, et al. Systematic review: The safety and efficacy of hyperbaric oxygen therapy for inflammatory bowel disease. *Aliment Pharmacol Ther.* Jun 2014;39(11):1266-1275. PMID 24738651
38. Pagoldh M, Hultgren E, Arnell P, et al. Hyperbaric oxygen therapy does not improve the effects of standardized treatment in a severe attack of ulcerative colitis: a prospective randomized study. *Scand J Gastroenterol.* Sep 2013;48(9):1033-1040. PMID 23879825
39. Lewis JD, Chuai S, Nessel L, et al. Use of the noninvasive components of the Mayo score to assess clinical response in ulcerative colitis. *Inflamm Bowel Dis.* Dec 2008;14(12):1660-1666. PMID 18623174
40. Bennett MH, Kertesz T, Perleth M, et al. Hyperbaric oxygen for idiopathic sudden sensorineural hearing loss and tinnitus. *Cochrane Database Syst Rev.* Oct 17 2012;10:CD004739. PMID 23076907
41. Cvorovic L, Jovanovic MB, Milutinovic Z, et al. Randomized prospective trial of hyperbaric oxygen therapy and intratympanic steroid injection as salvage treatment of sudden sensorineural hearing loss. *Otol Neurotol.* Aug 2013;34(6):1021-1026. PMID 23820795
42. Bennett M, Best TM, Babul S, et al. Hyperbaric oxygen therapy for delayed onset muscle soreness and closed soft tissue injury. *Cochrane Database Syst Rev.* Oct 19 2005(4):CD004713. PMID 16235376
43. Xiong T, Chen H, Luo R, et al. Hyperbaric oxygen therapy for people with autism spectrum disorder (ASD). *Cochrane Database Syst Rev.* Oct 13 2016;10:CD010922. PMID 27737490
44. Sampanthavivat M, Singkhwa W, Chaiyakul T, et al. Hyperbaric oxygen in the treatment of childhood autism: a randomised controlled trial. *Diving Hyperb Med.* Sep 2012;42(3):128-133. PMID 22987458
45. Lacey DJ, Stolfi A, Pilati LE. Effects of hyperbaric oxygen on motor function in children with cerebral palsy. *Ann Neurol.* Nov 2012;72(5):695-703. PMID 23071074

46. Collet JP, Vanasse M, Marois P, et al. Hyperbaric oxygen for children with cerebral palsy: a randomised multicentre trial. HBO-CP Research Group. *Lancet.* Feb 24 2001;357(9256):582-586. PMID 11558483
47. Long Y, Tan J, Nie Y, et al. Hyperbaric oxygen therapy is safe and effective for the treatment of sleep disorders in children with cerebral palsy. *Neurol Res.* Mar 2017;39(3):239-247. PMID 28079475
48. Xiao Y, Wang J, Jiang S, et al. Hyperbaric oxygen therapy for vascular dementia. *Cochrane Database Syst Rev.* Jul 11 2012;7(7):CD009425. PMID 22786527
49. Spiegelberg L, Djasim UM, van Neck HW, et al. Hyperbaric oxygen therapy in the management of radiation-induced injury in the head and neck region: a review of the literature. *J Oral Maxillofac Surg.* Aug 2010;68(8):1732-1739. PMID 20493616
50. Teguh DN, Levendag PC, Noever I, et al. Early hyperbaric oxygen therapy for reducing radiotherapy side effects: early results of a randomized trial in oropharyngeal and nasopharyngeal cancer. *Int J Radiat Oncol Biol Phys.* Nov 1 2009;75(3):711-716. PMID 19386439
51. Gothard L, Haviland J, Bryson P, et al. Randomised phase II trial of hyperbaric oxygen therapy in patients with chronic arm lymphoedema after radiotherapy for cancer. *Radiother Oncol.* Oct 2010;97(1):101-107. PMID 20605648
52. Camporesi EM, Vezzani G, Bosco G, et al. Hyperbaric oxygen therapy in femoral head necrosis. *J Arthroplasty.* Sep 2010;25(6 Suppl):118-123. PMID 20637561
53. Bennett MH, French C, Schnabel A, et al. Normobaric and hyperbaric oxygen therapy for the treatment and prevention of migraine and cluster headache. *Cochrane Database Syst Rev.* Dec 28 2015(12):CD005219. PMID 26709672
54. Peng Z, Wang S, Huang X, et al. Effect of hyperbaric oxygen therapy on patients with herpes zoster. *Undersea Hyperb Med.* Nov-Dec 2012;39(6):1083-1087. PMID 23342765
55. Efrati S, Golan H, Bechor Y, et al. Hyperbaric oxygen therapy can diminish fibromyalgia syndrome--prospective clinical trial. *PLoS One.* May 2015;10(5):e0127012. PMID 26010952
56. Yildiz S, Kiralp MZ, Akin A, et al. A new treatment modality for fibromyalgia syndrome: hyperbaric oxygen therapy. *J Int Med Res.* May-Jun 2004;32(3):263-267. PMID 15174219
57. Bennett M, Heard R. Hyperbaric oxygen therapy for multiple sclerosis. *CNS Neurosci Ther.* Apr 2010;16(2):115-124. PMID 20415839
58. Bennett M, Feldmeier J, Smee R, et al. Hyperbaric oxygenation for tumour sensitisation to radiotherapy. *Cochrane Database Syst Rev.* Oct 19 2005(4):CD005007. PMID 16235387
59. Bennett MH, Feldmeier J, Smee R, et al. Hyperbaric oxygenation for tumour sensitisation to radiotherapy. *Cochrane Database Syst Rev.* Apr 18 2012(4):CD005007. PMID 22513926
60. Heys SD, Smith IC, Ross JA, et al. A pilot study with long term follow up of hyperbaric oxygen pretreatment in patients with locally advanced breast cancer undergoing neo-adjuvant chemotherapy. *Undersea Hyperb Med.* Jan-Feb 2006;33(1):33-43. PMID 16602255
61. Huang ET, Mansouri J, Murad MH, et al. A clinical practice guideline for the use of hyperbaric oxygen therapy in the treatment of diabetic foot ulcers. *Undersea Hyperb Med.* May-Jun 2015;42(3):205-247. PMID 26152105
62. Lipsky BA, Berendt AR, Cornia PB, et al. 2012 infectious diseases society of america clinical practice guideline for the diagnosis and treatment of diabetic foot infections. *J Am Podiatr Med Assoc.* Jan-Feb 2013;103(1):2-7. PMID 23328846
63. Hingorani A, LaMuraglia GM, Henke P, et al. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. *J Vasc Surg.* Feb 2016;63(2 Suppl):3S-21S. PMID 26804367
64. Weaver LK, editor. *Hyperbaric Oxygen Therapy Indications. 13th ed.* North Palm Beach, FL: Undersea and Hyperbaric Medical Society; 2014.
65. Feldmeier JJ, Hopf HW, Warriner RA, 3rd, et al. UHMS position statement: topical oxygen for chronic wounds. *Undersea Hyperb Med.* May-Jun 2005;32(3):157-168. PMID 16119307
66. Bennett M., Heard R. *UHMS Position Paper: the treatment of multiple sclerosis with hyperbaric oxygen therapy.* North Palm Beach, FL: Undersea & Hyperbaric Medical Society (UHMS); n.d.
67. Bennett M., B. H. *UHMS Position Paper: the treatment of autism spectrum disorder with hyperbaric oxygen therapy.* North Palm Beach, FL: Undersea & Hyperbaric Medical Society (UHMS); 2009.
68. American Academy of Otolaryngology-Head and Neck Surgery. Clinical practice guideline: sudden hearing loss. 2012; https://www.entnet.org/sites/default/files/SHL-talking-points-physicians.pdf. Accessed November 21, 2017.
69. Mathieu D, Marroni A, Kot J. Tenth European Consensus Conference on Hyperbaric Medicine: recommendations for accepted and non-accepted clinical indications and practice of hyperbaric oxygen treatment. *Diving Hyperb Med.* Mar 2017;47(1):24-32. PMID 28357821

70. Sultan A, Hanna GJ, Margalit DN, et al. The use of hyperbaric oxygen for the prevention and management of osteoradionecrosis of the jaw: a Dana-Farber/Brigham and Women's Cancer Center Multidisciplinary Guideline. *Oncologist.* Mar 2017;22(3):343-350. PMID 28209748
71. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Hyperbaric Oxygen Therapy (20.29). 2006; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=12&ncdver=3&bc=AAAAgAAAAAAAAA%3d%3d&. Accessed November 21, 2017.

POLICY HISTORY

Date	Action	Description
September 2012	New Policy	
March 2014	Update Policy	Policy updated with literature review. Bisphosphonate-related osteonecrosis of the jaw, motor dysfunction associated with stroke, herpes zoster and vascular dementia added as not medically necessary. References added; other references renumbered or removed. Additional conditions added as medically necessary.
December 2014	Update Policy	Policy updated with literature review through July 17, 2014. In investigational statement, severe or refractory Crohn's disease changed to inflammatory bowel disease (Crohn disease or ulcerative colitis). Clarification added to bullet point in not medically necessary statement on radiation-induced injury in the head and neck. Title changed from "Hyperbaric Oxygen Pressurization (HBO)" to "Hyperbaric Oxygen Therapy". References 2, 10, 12-13, 43-46, and 49 added.
December 2015	Update Policy	Policy updated with literature review through June 17, 2015; references 27, 34, 40, 41 and 66-70 added. Bullet points on (1) fibromyalgia and (2) mental illness (ie, posttraumatic stress disorder, generalized anxiety disorder or depression) added to the not medically necessary statement.
March 2017	Update Policy	Policy updated with literature review through November 8, 2016; references 6-7, 15, 22, 26-27, 39, 48, and 56 added. Policy statements unchanged.
March 2018	Update Policy	Policy updated with literature review through November 6, 2017; references 1, 3, 12-13, 47, 58-59, 62-63, 65-67, and 69-70 added. Policy statements unchanged.