

Corporate Medical Policy

Hyperbaric Oxygen Therapy

File Name: hyperbaric_oxygen_therapy
Origination: 4/1980
Last Review: 10/2024

Description of Procedure or Service

Hyperbaric oxygen therapy (HBOT) is a technique of delivering higher pressures of oxygen to the tissues. Two methods of administration are available: systemic and topical.

In systemic or large hyperbaric oxygen chambers, the patient is entirely enclosed in a pressure chamber and breathes oxygen at a pressure greater than 1 atmosphere (the pressure of oxygen at sea level). Thus, this technique relies on systemic circulation to deliver highly oxygenated blood to the target site, typically a wound. In addition, systemic hyperbaric oxygen therapy 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 monoplace chamber pressurized with pure oxygen or in a larger, multiplace chamber pressurized with compressed air, in which case the patient receives pure oxygen by mask, head tent, or endotracheal tube.

Topical hyperbaric oxygen therapy (topical HBOT) also known as topical oxygen or topical wound oxygen therapy (TWO2) is a technique of delivering 100% oxygen directly to an open, moist wound at a pressure slightly higher than atmospheric pressure. It is hypothesized that the high concentrations of oxygen diffuse directly into the wound to increase the local cellular oxygen tension, which in turn promotes wound healing. Topical hyperbaric oxygen devices consist of an appliance to enclose the wound area (frequently an extremity) and a source of oxygen; conventional oxygen tanks may be used. The appliances may be disposable and may be used without supervision in the home by well-trained patients. Topical hyperbaric oxygen therapy has been investigated as a treatment of skin ulcerations resulting from diabetes, venous stasis, postsurgical infection, gangrenous lesion, decubitus ulcers, amputations, skin graft, burns, or frostbite.

HBOT is a generally safe therapy, with an estimated adverse side effect of 0.4%. Adverse events may occur either from pressure effects or the oxygen. The pressure effect (barotrauma) may affect any closed air-filled cavity such as ears, sinus, teeth, and lungs. Pain and/or swelling may occur at these sites as pressure increases during the procedure and decreases as the procedure is ending. Oxygen toxicity may affect the pulmonary, neurologic, or ophthalmologic systems. Pulmonary symptoms include a mild cough, substernal burning, and dyspnea. Neurologic effects include tunnel vision, tinnitus, nausea and dizziness. Ophthalmologic effects include retinopathy in neonates, cataract formation and transient myopic vision changes.

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. 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.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Hyperbaric Oxygen Therapy

Policy

BCBSNC will cover systemic Hyperbaric Oxygen Therapy treatment when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Topical Hyperbaric Oxygen Therapy is considered investigational. BCBSNC does not cover investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore, member benefit language should be reviewed before applying the terms of this medical policy.

When hyperbaric oxygen therapy is covered

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

- 1) non-healing diabetic wounds of the lower extremities in individuals who:
 - have type I or type II diabetes and a lower extremity wound due to diabetes,
 - have a wound classified as Wagner grade 3 or higher*; and
 - have no measurable signs of healing after 30 days of an adequate course of standard wound therapy.
- 2) acute traumatic ischemia (e.g., crush injuries, reperfusion injury, compartment syndrome).
- 3) decompression sickness
- 4) air or gas embolism, acute
- 5) cyanide poisoning, acute
- 6) carbon monoxide poisoning
- 7) soft-tissue radiation necrosis (e.g., radiation enteritis, cystitis, proctitis) and osteoradionecrosis
- 8) pre-treatment and post-treatment for individuals undergoing dental surgery (non-implant related) of an irradiated jaw
- 9) gas gangrene (clostridial myonecrosis)
- 10) profound anemia with exceptional blood loss: only when blood transfusion is impossible or must be delayed
- 11) chronic refractory osteomyelitis
- 12) compromised skin grafts or flaps
- 13) necrotizing soft-tissue infections
- 14) moderate to profound idiopathic sudden sensorineural hearing loss, when treatment is within three months of diagnosis
- 15) intracranial abscesses
- 16) acute thermal burns
- 17) Avascular necrosis (aseptic osteonecrosis)
- 18) arterial insufficiencies:
 - central retinal artery occlusion, or
 - enhancement of healing in selected problem wounds

* The Wagner classification system of wounds is defined 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

Hyperbaric Oxygen Therapy

such a percentage that no local procedures are possible and amputation (at least at the below the knee level) is indicated.

When hyperbaric oxygen therapy is not covered

Topical hyperbaric oxygen therapy is considered investigational for all indications.

Hyperbaric oxygen therapy is considered investigational in the treatment of all other conditions, except those listed above as covered

Policy Guidelines

In 2023, the Undersea and Hyperbaric Medical Society (UHMS) updated their list of indications considered appropriate for HBOT. These indications are as follows:

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
 - Central retinal artery occlusion
 - Enhancement of healing in selected problem wounds
7. Severe anemia
8. Intracranial abscess
9. Necrotizing soft tissue infections
10. Osteomyelitis (refractory)
11. Delayed radiation injury (soft tissue and bony necrosis)
12. Skin grafts and flaps (compromised)
13. Acute thermal burn injury
14. Idiopathic sudden sensorineural hearing loss (ISSNHL) (individuals with moderate to profound ISSNHL)
15. Diabetic foot ulcer
16. Avascular necrosis (aseptic osteonecrosis)

UHMS has also published position statements that concluded there was insufficient evidence to recommend topical HBOT for chronic wounds, multiple sclerosis, and autism spectrum disorder.

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

Hyperbaric Oxygen Therapy

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).

Summary of Evidence

For individuals with wounds, burns or infections who receive topical HBOT, the evidence includes a systematic review, case series, and three subsequent RCTs not included in the systematic review. Relevant outcomes are overall survival, symptoms, change in disease status, and functional outcomes. The systematic review identified 3 RCTs including patients with sacral pressure ulcers, ischial pressure ulcers, and refractory venous ulcers. All trials in the systematic review reported improved healing with HBOT, but there was heterogeneity in the patient populations and treatment regimens. Two RCTs not included in the systematic review did not provide sufficient data that topical HBOT is efficacious, as neither showed significant improvement in wound healing or limb salvage. A 2019 sham-controlled, double blind RCT found adjunctive therapy with topical oxygen resulted in greater healing of chronic diabetic foot ulcers than standard of care alone at 12 weeks and 12 months. However, at 12 months no statistical difference in ulcer recurrence was found, and the study was limited by its small population. A large longitudinal observational cohort study of over 6,000 patients with topical oxygen usage showed no improvement in foot ulcer healing and were more likely to have an amputation. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with chronic diabetic ulcers who receive systemic HBOT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms and change in disease status. Meta-analyses of RCTs found significantly higher diabetic ulcer healing rates with HBOT than with control conditions. Two of the 3 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 Meta-analysis, RCTs and a systematic review. Relevant outcomes are overall survival and symptoms. 2018 meta-analysis by Lin found HBOT resulted in lower incidence of neuropsychological sequelae, including headache, memory impairment, difficulty concentrating, disturbed sleep, and delayed neurological sequelae. 2019 UHMS guidelines give an IIa recommendation with a level of evidence A. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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. 2019 UHMS guidelines give an IIa/IIb recommendation with a level of evidence B-NR. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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.

Hyperbaric Oxygen Therapy

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. Several retrospective studies have shown evidence that HBOT reduces mortality. 2019 UHMS guidelines gave a I recommendation with level of evidence B-NR for Clostridial Myonecrosis and an IIa recommendation with level of evidence B-NR for Necrotizing Fasciitis. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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.

Hyperbaric Oxygen Therapy

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 Meta-analysis, RCTs and a systematic review. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Hearing recovery and absolute hearing gain was significantly higher with HBOT use than without. 2019 UHMS guidelines support HBOT use for idiopathic sudden sensorineural hearing loss. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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.

Hyperbaric Oxygen Therapy

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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 99183, A4575, E0446, G0277

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Hyperbaric Oxygen Therapy

Scientific Background and Reference Sources

For policy titled “Hyperbaric Oxygen Pressurization”

BCBSA Medical Policy Reference Manual - 12/1/95 BCBSA Medical Policy Reference Manual - 11/98 Medical Policy Advisory Group - 3/99

TEC Assessment - 10/20/99

BCBSA Medical Policy Reference Manual - 2/2000 Independent Consultant Review - 5/2000

Medical Policy Advisory Group - 6/2000 Medical Policy Advisory Group - 9/2001

BCBSA Medical Policy Reference Manual, 2.01.04, 7/12/02 Specialty Matched Consultant Advisory Panel - 4/2003

ECRI Windows on Medical Technology. Hyperbaric Oxygen Therapy for Chronic Wound Healing, Issue No. 59, October 2001

ECRI Windows on Medical Technology. Topical Oxygen Therapy for Chronic Wound Healing, Issue No. 54, September 2001.

Medicare Coverage Issues Manual from CMS website. Retrieved from http://www.cms.gov/manuals/06_cim/ci35.asp#_35_10 on April 23, 2003.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 12/17/2003. BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 10/10/06.

Centers for Medicare & Medicaid Services. NCD for Hyperbaric Oxygen Therapy (20.29). Effective 6/19/

06. Retrieved 1/9/07 from http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=20.29&ncd_version=3

Agency for Healthcare Research and Quality (AHRQ). Hyperbaric oxygen therapy for brain injury, cerebral palsy, and stroke. Evidence Report/Technology Assessment Number 85 (September 2003). Retrieved 1/9/07 from <http://www.ahrq.gov/downloads/pub/evidence/pdf/hypox/hyperox.pdf>

Agency for Healthcare Research and Quality (AHRQ). A Horizon Scan: Uses of Hyperbaric Oxygen Therapy. Technology Assessment (October 5, 2006). Retrieved 1/9/07 from <http://www.cms.hhs.gov/determinationprocess/downloads/id42TA.pdf>

Ontario Health Technology Advisory Committee (OHTAC). Hyperbaric oxygen therapy for non-healing ulcers in diabetes mellitus (September 2005). Retrieved 1/9/07 from http://www.health.gov.on.ca/english/providers/program/mas/tech/recommend/rec_hypox_081105.pdf

Medical Services Advisory Committee. MSAC application 1054: Hyperbaric oxygen therapy (HBOT) for the treatment of non-healing wounds in non-diabetic patients and refractory soft tissue radiation injuries (May 2003). Retrieved 1/19/07 from [http://www.msac.gov.au/internet/msac/publishing.nsf/Content/91F410BBC4FD6F3CA257163001606B9/\\$File/msac1054.pdf](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/91F410BBC4FD6F3CA257163001606B9/$File/msac1054.pdf)

Medical Services Advisory Committee. MSAC applications 1018-1020: Hyperbaric oxygen therapy (November 2000). Retrieved 1/19/07 from

Hyperbaric Oxygen Therapy

[http://www.msac.gov.au/internet/msac/publishing.nsf/Content/FBB465EE76FBE5FDCA25716300026A40/\\$File/msac1018_1020.pdf](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/FBB465EE76FBE5FDCA25716300026A40/$File/msac1018_1020.pdf)

American Cancer Society (June 2005). Hyperbaric oxygen therapy. Retrieved 1/24/07 from http://www.cancer.org/docroot/ETO/content/ETO_t_3xHyperbaric_oxygen_therapy.asp?s

American College of Hyperbaric Medicine (2005). Accepted Indications. Retrieved 1/24/07 from <http://www.hyperbaricmedicine.org/Preferred%20Protocols.htm>

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 3/13/08

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 2/11/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 8/12/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 2/9/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 8/9/2012

Senior Medical Director – 10/2012

Specialty Matched Consultant Advisory Panel – 1/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 8/8/2013

Senior Medical Director – 9/2013

Senior Medical Director- December 2014

Specialty Matched Consultant Advisory Panel – 1/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 8/14/2014

Undersea & Hyperbaric Medical Society. Hyperbaric Oxygen Therapy Indications: 13th Edition. Retrieved 11/19/2014 from <http://membership.uhms.org/?page=Indications>

Stachler RJ, Chandrasekhar SS, Archer SM, et al; American Academy of Otolaryngology-Head and Neck Surgery. Clinical practice guideline: sudden hearing loss. Otolaryngol Head Neck Surg. 2012. <http://www.guideline.gov/content.aspx?id=36054>

For policy titled, “Hyperbaric Oxygen Therapy”

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 8/13/2015 Specialty Matched Consultant Advisory Panel 1/2016

Medical Director 1/ 2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 1/12/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 1/11/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 1/17/2019

Rhee TM, Hwang D, Lee JS, et al. Addition of Hyperbaric Oxygen Therapy vs Medical Therapy Alone for Idiopathic Sudden Sensorineural Hearing Loss: A Systematic Review and Meta-analysis. JAMA Otolaryngol Head Neck Surg. Sep 27 2018. PMID 30267033

Hyperbaric Oxygen Therapy

Lin CH, Su WH, Chen YC, et al. Treatment with normobaric or hyperbaric oxygen and its effect on neuropsychometric dysfunction after carbon monoxide poisoning: A systematic review and meta-analysis of randomized controlled trials. *Medicine (Baltimore)*. 2018;97(39):e12456.

Soh CR, Pietrobon R, Freiburger JJ, et al. Hyperbaric oxygen therapy in necrotising soft tissue infections: a study of patients in the United States Nationwide Inpatient Sample. *Intensive Care Med*. 2012 Jul;38(7):1143-51.

Shaw JJ, Psinos C, Emhoff TA, et al. Not just full of hot air: hyperbaric oxygen therapy increases survival in cases of necrotizing soft tissue infections. *Surg Infect (Larchmt)*. 2014 Jun;15(3):328-35.

Devaney B, Frawley G, Frawley L, et al. Necrotising soft tissue infections: the effect of hyperbaric oxygen on mortality. *Anaesth Intensive Care*. 2015 Nov;43(6):685-92.

Steiner T, Seiffart A, Schumann J, Bucher M. Hyperbaric oxygen therapy in necrotizing soft tissue infections: A retrospective study. *Adv Exp Med Biol*. 2018;1072:263-7

Undersea and Hyperbaric Medical Society. (2019). *Indications for Hyperbaric Oxygen Therapy*. Retrieved from <https://www.uhms.org/resources/hbo-indications.html>

Frykberg RG, Franks PJ, Edmonds M, et al. A Multinational, Multicenter, Randomized, Double-Blinded, Placebo-Controlled Trial to Evaluate the Efficacy of Cyclical Topical Wound Oxygen Therapy (TWO2) in the Treatment of Chronic Diabetic Foot Ulcers: The TWO2 Study. *Diabetes Care* Oct 2019, dc190476; **DOI:** 10.2337/dc19-0476

Fedorko L, Bowen JM, Jones W, et al. Hyperbaric oxygen therapy does not reduce indications for amputation in patients with diabetes with nonhealing ulcers of the lower limb: a prospective, double-blind, randomized controlled clinical trial. *Diabetes Care* 2016;39:392–399

Santema KTB, Stoekenbroek RM, Koelemay MJW, et al.; DAMO2CLES Study Group. Hyperbaric oxygen therapy in the treatment of ischemic lower-extremity ulcers in patients with diabetes: results of the DAMO2CLES multicenter randomized clinical trial. *Diabetes Care* 2018;41:112–119

Margolis DJ, Gupta J, Hoffstad O, et al. Lack of effectiveness of hyperbaric oxygen therapy for the treatment of diabetic foot ulcer and the prevention of amputation: a cohort study. *Diabetes Care* 2013;36:1961–1966

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 1/16/2020

Specialty Matches Consultant Advisory Panel 10/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.04, 06/2021

Specialty Matches Consultant Advisory Panel 10/2021

Medical Director Review 10/2021

Specialty Matches Consultant Advisory Panel 10/2022

Medical Director Review 10/2022

U.S. Food and Drug Administration. Hyperbaric Oxygen Therapy: Don't Be Misled. 2013; <https://www.talkingaboutthescience.com/studies/FDA2013.pdf>

Hyperbaric Oxygen Therapy

Moon RE, editor. Hyperbaric Oxygen Therapy Indications. 14th ed. North Palm Beach, FL: Undersea and Hyperbaric Medical Society; 2019.

Specialty Matches Consultant Advisory Panel 10/2023

Medical Director Review 10/2023

Undersea and Hyperbaric Medical Society. Hyperbaric Medicine Indications Manual, 15th Edition. Enoch T. Huang (Ed). Published by Best Publishing, 2023. ISBN: 978-1-947239-42-5. <https://www.uhms.org/resources/featured-resources/hbo-indications.html>.

Specialty Matches Consultant Advisory Panel 10/2024

Medical Director Review 10/2024

Policy Implementation/Update Information

For policy titled, “Hyperbaric Oxygen Pressurization”

4/80	Original policy
3/83	Reaffirmed: List of experimental/Investigative indications added.
6/84	Reaffirmed.
8/92	Revised
4/96	Revised: Combined local and national policies. Added indication for patients who have undergone radiation to the head and neck requiring full mouth extraction. Investigation diagnosis for prophylactic Hyperbaric Oxygen following radiation therapy added.
4/97	Reaffirmed
3/99	Revised: Added statement that topical hyperbaric oxygen therapy is considered investigational. Reaffirmed by MPAG.
5/99	Reformatted, Procedural description changed, Medical Term Definitions added.
11/99	Reviewed. Indications changed per update from TEC review on 10/99.
5/00	Revised: Indications changed per update from the BCBSA, TEC review, and Independent Consultant recommendations. Compromised skin grafts or flaps and acute thermal burns are non-covered indications.
6/00	Medical Policy Advisory Group 7/00 System coding changes
9/01	Medical Policy Advisory Group review. No changes to criteria. 3/02 Coding Format Change.
5/03	Specialty Matched Consultant Advisory Panel review. New sources added to the policy. No changes to policy. Reaffirm.

Hyperbaric Oxygen Therapy

- 7/03 Format change. Removed ® and replaced with bullets in the covered and not covered section of the policy.
- 4/04 Benefits Application and Billing/Coding sections updated for consistency.
- 4/7/05 Specialty Matched Consultant Advisory Panel [MPAG] review on 3/10/05. No changes made in policy criteria. Code descriptions removed from Billing/Coding section. Reference added.
- 6/4/07 Definition of Topical Hyperbaric Oxygen therapy added to Description section. Note: topical hyperbaric oxygen therapy is not considered hyperbaric oxygen pressurization. (See separate policy titled "Topical Hyperbaric Oxygen Therapy" MED1431). Indications for use of hyperbaric oxygen pressurization have been revised in the Covered and Noncovered sections. Wagner classification of wounds added to Covered section. The following statements were added to the Policy Guidelines section: While evidence for the treatment of acute carbon monoxide poisoning with HBO pressurization has failed to demonstrate improved health outcomes, this technology is accepted in medical practice as a standard medical therapy for the treatment of carbon monoxide poisoning. Code A4575 deleted. References updated. Specialty Matched Consultant Advisory Panel review 3/15/07, policy changes accepted as written. Notification given 6/4/07. Effective date 8/13/07. (adn)
- 5/5/08 Indications in the When Covered and When Not Covered sections converted from bulleted list to numbered list. The following indications added to the When Covered section: Item 6) soft- tissue radiation necrosis (radiation enteritis, cystitis, proctitis) and osteoradionecrosis and Item 7) pre-treatment and post-treatment for patients undergoing dental surgery (non-implant related) of an irradiated jaw. The following indications are deleted from the Not Covered section: cystitis enteritis or proctitis and radiation necrosis (osteoradionecrosis and soft-tissue radiation necrosis). (adn)
- 4/27/09 Routine biennial review. Specialty Matched Consultant Advisory Panel review meeting 3/26/09. No change to policy statement.
- 9/14/10 Added the following to the list of non-covered indications in the When HBO is Not Covered section: "early treatment (beginning at completion of radiation therapy) to reduce side effects of radiation therapy and autism spectrum disorders." Notification given 9/14/2010 for effective date of 12/21/2010. (adn)
- 4/26/11 Acute carbon monoxide poisoning and chronic refractory osteomyelitis added to the When HBO Is Covered section. Policy Guidelines sections updated with rationale. (adn)
- 10/30/12 Description section revised. The following statement was added to the Policy section: "Topical Hyperbaric Oxygen Therapy is considered investigational. BCBSNC does not cover investigational services." Acute osteomyelitis, acute surgical and traumatic wounds, idiopathic femoral neck necrosis, chronic wounds, other than those in patients with diabetes who meet the criteria specified in the medically necessary statement, acute ischemic stroke, Bell's palsy, and chronic arm lymphedema following radiotherapy for cancer added to the list of non-covered indications in the When HBO is Not Covered section. Utilization of hyperbaric oxygen information added to Policy Guidelines Section. Summary statements for Hyperbaric Oxygen Therapy and Topical Hyperbaric Oxygen Therapy added to Policy Guidelines Section. Added HCPCS code A4575 and E0446 to Billing/Coding section. Senior Medical Director review 10/14/2012. Notification given 10/30/2012 for effective date of 1/29/2013. (btw).
- 1/29/13 Specialty Matched Consultant Advisory Panel. No change to policy. (btw)
- 10/1/13 Added the following indications as investigational to the When Not Covered section: "Bisphosphonate-related osteonecrosis of the jaw, motor dysfunction associated with

Hyperbaric Oxygen Therapy

- stroke, herpes zoster and vascular dementia”. Senior Medical Director review 9/14/2013. Reference added. Notification given 10/1/2013. Policy effective 12/10/2013. (btw)
- 2/11/14 Specialty Matched Consultant Advisory Panel review 1/28/2014. No change to policy. (btw)
- 12/30/14 Added HCPCS code G0277 to Billing/Coding section effective as of 1/1/15. No change to policy. (td)
- 1/27/15 References updated. Description section updated. When Covered section updated to include: chronic refractory osteomyelitis, compromised skin grafts or flaps, necrotizing soft-tissue infections, severe anemia, idiopathic sudden sensorineural hearing loss, intracranial abscesses, acute thermal burns, arterial insufficiencies: central retinal artery occlusion and enhancement of healing in selected problem wounds. Policy Guidelines section updated. Senior Medical Director review 12/2014. Specialty Matched Consultant Advisory Panel review 1/2015. (td)

For policy titled, “Hyperbaric Oxygen Therapy”

- 2/29/16 Policy name changed from “Hyperbaric Oxygen Pressurization” to “Hyperbaric Oxygen Therapy”. Description section updated. References updated. Matched Consultant Advisory Panel review 1/27/2016. Medical Director review 1/2016. (td)
- 12/30/16 Specialty Matched Consultant Advisory Panel review 11/30/2016. No change to policy statement. (an)
- 12/15/17 Specialty Matched Consultant Advisory Panel review 11/29/2017. No change to policy statement. (an)
- 11/9/18 Updated Description Section. Updated Policy Guidelines section. Specialty Matched Consultant Advisory Panel review 10/24/2018. No change to policy statement. (an)
- 10/29/19 Reference and Policy Guideline section updated. Specialty Matched Consultant Advisory Panel review 10/16/2019. No change to policy statement. (eel)
- 12/31/19 Policy Guidelines and Description of Service updated. References added. No change to policy statement. (eel)
- 11/10/20 Specialty Matched Consultant Advisory Panel review 10/21/2020. References updated. No change to policy statement. (eel)
- 11/2/21 References updated. Specialty Matched Consultant Advisory Panel review 10/2021. Medical Director review 10/2021. References updated. No change to policy statement. (tt)
- 11/1/22 Minor updates to policy guidelines. References updated. Specialty Matched Consultant Advisory Panel review 10/2022. Medical Director review 10/2022. No change to policy statement. (tt)
- 11/7/23 Regulatory status updated. Updated “patients” to “individuals” in coverage criteria. References updated. Specialty Matched Consultant Advisory Panel review 10/2023. Medical Director review 10/2023. No change to policy statement. (tt)
- 10/30/24 References updated. When covered section updated to include “avascular necrosis (aseptic osteonecrosis)” as an indication for coverage based on updated guidelines from Undersea and Hyperbaric Medical Society. Policy guidelines updated. Specialty Matched Consultant

Hyperbaric Oxygen Therapy

Advisory Panel review 10/2024. Medical Director review 10/2024. No change to policy statement. (tt)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.