BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Hyperbaric Oxygen Pressurization

File Name:	hyperbaric_oxygen_pressurization
Origination:	4/1980
Last CAP Review:	3/2009
Next CAP Review:	11/2011
Last Review:	4/2011

Description of Procedure or Service

Hyperbaric oxygen pressurization (HBO) is a technique of delivering higher pressures of oxygen to the tissues. The patient is entirely enclosed in a pressure chamber and breathes oxygen at a pressure greater than one atmosphere (the pressure of oxygen at sea level). This technique relies on the body's circulation of blood to deliver highly oxygenated blood to the target site. The treatment may be carried out either in a monoplace chamber pressurized with pure oxygen or a large 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 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 due to diabetes, venous stasis, postsurgical infection, gangrenous lesion, decubitus ulcers, amputations, skin graft, burns, or frostbite. Breathing 100% oxygen at one atmosphere pressure or applying oxygen topically to parts of the body without the use of a pressurized chamber, which encloses the patient completely, is not considered hyperbaric oxygen pressurization. (See separate policy titled "Topical Hyperbaric Oxygen Therapy")

******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.***

Policy

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

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.

Hyperbaric Oxygen Pressurization

When Hyperbaric Oxygen Pressurization is covered

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

1) non-healing diabetic wounds of the lower extremities in patients 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
3) decompression sickness
4) gas embolism, acute
5) cyanide poisoning, acute
6) acute carbon monoxide poisoning
7) soft-tissue radiation necrosis (e.g., radiation enteritis, cystitis, proctitis) and osteoradionecrosis
8) pre-treatment and post-treatment for patients 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

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

When Hyperbaric Oxygen Pressurization is not covered

Topical hyperbaric oxygen therapy is considered investigational.

Hyperbaric oxygen pressurization is considered investigational in the treatment of the following

1) compromised skin grafts or flaps
2) acute osteomyelitis, refractory to standard medical management
3) necrotizing soft-tissue infections
4) acute thermal burns
5) spinal cord injury
6) traumatic brain injury
7) severe or refractory Crohn’s disease
8) brown recluse spider bites
9) bone grafts
10) carbon tetrachloride poisoning, acute
11) cerebrovascular disease, acute (thrombotic or embolic) or chronic
12) fracture healing
13) hydrogen sulfide poisoning
14) intra-abdominal and intracranial abscesses
15) lepromatous leprosy

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16) meningitis
17) pseudomembranous colitis (antimicrobial agent-induced colitis)
18) radiation myelitis
19) sickle cell crisis and/or hematuria
20) demyelinating diseases (multiple sclerosis, amyotrophic lateral sclerosis)
21) retinal artery insufficiency, acute
22) retinopathy, adjunct to scleral buckling procedures in patients with sickle cell peripheral retinopathy and retinal detachment
23) pyoderma gangrenosum
24) acute arterial peripheral insufficiency
25) acute coronary syndromes and as an adjunct to coronary interventions, including but limited to percutaneous coronary interventions and cardiopulmonary bypass
26) idiopathic sudden sensorineural hearing loss
27) refractory mycoses (mucomycosis, actinomycosis, canidiobolus coronato)
28) cerebral edema, acute
29) migraine
30) invitro fertilization
31) cerebral palsy
32) tumor sensitization for cancer treatments, including but not limited to radiotherapy or chemotherapy
33) delayed onset muscle soreness
34) early treatment (beginning at completion of radiation therapy) to reduce side effects of radiation therapy; and
35) autism spectrum disorder

Policy Guidelines

An updated search of the literature (through May 2010) is summarized in the following section.

Chronic Wounds: No evidence was found to demonstrate benefits of HBO for arterial, venous, or pressure ulcers or wounds or other pathologies due to limited trial data. However, trials showed that HBO significantly reduced the risk of major amputations from diabetic ulcers.

Carbon Monoxide Poisoning: In light of recent clinical studies, and given the strong clinical support for this treatment, the use of HBO for acute carbon monoxide poisoning may be considered medically necessary.

Radionecrosis and Osteoradionecrosis: There is a definite need for more randomized controlled trials (RCTs) to ascertain the effectiveness of HBO in irradiated patients requiring dental implants. Given the longstanding use of this technology and the existing literature base, the policy statement indicates that use of hyperbaric oxygen therapy for treatment of soft tissue and bone radiation necrosis and for pre- and post-treatment of dental surgery (non-implant-related) in an irradiated jaw may be considered medically necessary.

Osteomyelitis: Given the high percentage of refractory patients in clinical studies who had successful outcomes and the clinical support for HBO as a treatment option for chronic refractory osteomyelitis, the use of HBO therapy for chronic refractory osteomyelitis may be considered medically necessary. HBO treatment for acute osteomyelitis refractory to medical treatment remains investigational.

Compromised Skin Grafts and Flaps: There was limited published data and no RCTs regarding HBO for treatment of skin flaps and grafts. This indication is considered investigational.

Necrotizing Soft Tissue Infections: Research findings to date have been inconsistent. HBO use for

this indication is considered investigational.

Refractory Mycoses: No clinical trials on refractory mycoses (mucormycosis, actinomycosis, canidiobolus coronato) and cerebral edema were found. Therefore, these indications are considered investigational.

Acute Peripheral Arterial Insufficiency/Acute Coronary Syndromes/Stroke: The current evidence does not support use of HBO for these indications.

Hearing Loss: Data are insufficient to determine the clinical significance of hearing improvement with the use of HBO in patients with idiopathic sudden sensorineural hearing loss.

Migraine: One randomized, double-blind, placebo-controlled study reported no significant reductions in migraine occurrence with HBO compared to hyperbaric air treatments.

Amyotrophic Lateral Sclerosis: A small case series reported some improvements in fatigue but noted that further study is needed and attention to placebo effects must be given.

In Vitro Fertilization: No outcomes were reported in the one published study.

Cerebral Palsy: One study found that HBO produced similar improvements in outcomes such as gross motor function and activities of daily living as did treatment with slightly pressurized air.

Cancer Treatment: Studies in animal models have suggested that HBO increases tumor vascularity and may make chemotherapy more effective. HBO given with radiotherapy may be useful in tumor control; however, significant adverse effects are common with HBO. Further study is needed.

Autism Spectrum Disorders: One study reported only short term outcomes. The clinical significance is unclear. A placebo-controlled trial, including a 3 month follow-up is underway.

Radiotherapy Adverse Effects: The one study was limited by a small sample size and wide fluctuation over the follow-up period in quality of life ratings. This indication is considered investigational.

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 codes: 99183

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.

Scientific Background and Reference Sources

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_version3

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

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

Policy Implementation/Update Information

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.
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

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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)

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.