Hyperbaric Oxygen Therapy Indications
Thirteenth Edition
The Hyperbaric Oxygen Therapy Committee Report

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Copyright © 2014 Undersea and Hyperbaric Medical Society
Printed and bound in the United States of America
International Standard Book Number: 978-1930536-73-9
Published by:
Best Publishing Company
631 U.S. Highway 1, Suite 307
North Palm Beach, Florida 33408
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Preface

The application of air under pressure (hyperbaric air) in an effort to treat certain respiratory diseases dates back to 1662.[1] The medicinal uses of oxygen were first reported by Beddoes in 1794,[2] while the first article describing adjunctive uses of hyperbaric oxygen therapy (HBO₂) was written by Fontaine in 1879,[3] who constructed a mobile operating room which could be pressurized. He observed that pressurized patients were not as cyanotic after the use of nitrous oxide during surgery as compared to patients who had been treated in the traditional fashion. In addition, he noted that hernias were much easier to reduce. Also around that time, the work of Paul Bert[4] and J. Lorrain-Smith[5] showed that oxygen under pressure had potentially deleterious consequences on the human body with side effects that included central nervous system and pulmonary toxicity. The efforts of Churchill-Davidson and Boerema in the 1950s and 60s spurred the modern scientific use of clinical hyperbaric medicine.

In 1967, the Undersea Medical Society was founded by six United States Naval diving and submarine medical officers with the explicit goal of promoting diving and undersea medicine. In short order, this society expanded to include those interested in clinical hyperbaric medicine. In recognition of the dual interest by members in both diving and clinical applications of compression therapy, the society was renamed The Undersea and Hyperbaric Medical Society in 1986. It remains the leading not for profit organization dedicated to reporting scientifically and medically efficacious and relevant information pertaining to hyperbaric and undersea medicine.

In 1972, an ad hoc Medicare committee was formed to evaluate the efficacy of hyperbaric oxygen therapy for specified medical conditions. The focus was to determine if this treatment modality showed therapeutic benefit and merited insurance coverage. The growth of the body of scientific evidence that had developed over the preceding years supported this endeavor and recognition for the field. In 1976, the Hyperbaric Oxygen Therapy Committee became a standing committee of what was then the UMS. The first Hyperbaric Oxygen Committee Report was published in 1977 and served as guidance for practitioners and scientists interested in HBO₂. The report is usually published every three to five years and was last published in 2008. Additionally, this document continues to be used by the Centers for Medicare and Medicaid Services and other third party insurance carriers in determining payment.

The report, currently in its thirteenth edition, has grown in size and depth to reflect the evolution of the literature. To date, the committee recognizes fourteen indications. It is believed that the scientific evidence supports the use of HBO₂ for treatment of these medical conditions from both a clinical practice standpoint and insurance coverage perspective.

The Undersea and Hyperbaric Medical Society continues to maintain its reputation for its expertise on compression therapy. With leading experts authoring chapters in their respective fields, this publication continues to provide the most current and up to date guidance and support for scientists and practitioners of hyperbaric oxygen therapy.

John S. Peters, FACHE
President, Best Publishing Company
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William Zamboni MD
I. Background
The Undersea and Hyperbaric Medical Society (UHMS) is an international scientific organization which was founded in 1967 to foster exchange of data on the physiology and medicine of commercial and military diving. Over the intervening years, the interests of the society have expanded to include clinical hyperbaric oxygen therapy. The society has grown to over 2,000 members and has established the largest repository of diving and hyperbaric research collected in one place. Clinical information, books, technical reports, and an extensive bibliographic database of thousands of scientific papers represent the results of over 100 years of research by military and university laboratories around the world, and are contained in the UHMS Schilling Library, holdings which are now part of the Duke University Library, Durham, NC. The results of ongoing research and clinical aspects of undersea and hyperbaric medicine are reported annually at scientific meetings and published bi-monthly in Undersea and Hyperbaric Medicine. Historically, the society supported two journals, Undersea Biomedical Research and the Journal of Hyperbaric Medicine, which were merged in 1993.

The UHMS headquarters is located at:
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II. Hyperbaric Oxygen: Definition
The UHMS defines hyperbaric oxygen (HBO₂) as an intervention in which an individual breathes near 100% oxygen intermittently while inside a hyperbaric chamber that is pressurized to greater than sea level pressure (1 atmosphere absolute [ATA], which converts to 101.325 kilopascals [kPa]). For clinical purposes, the pressure must equal or exceed 1.4 ATA (141.86 kPa) while breathing near 100% oxygen. The United States Pharmacopoeia (USP) and Compressed Gas Association (CGA) Grade A specify medical grade oxygen to be not less than 99.0% by volume, and the National Fire Protection Association (NFPA) specifies USP medical grade oxygen.

In certain circumstances hyperbaric oxygen therapy represents the primary treatment modality while in others it is an adjunct to surgical or pharmacologic interventions.

The NFPA classifies chambers according to occupancy for the purposes of establishing minimum construction and operation requirements.¹

1) Class A – Human, multiple occupancy
2) Class B – Human, single occupancy
3) Class C – Animal, no human occupancy

Clinical treatments can be carried out in either a Class A (multi-) or Class B (mono-) chamber system. A Class A system holds two or more people (patients, observers, Photograph courtesy of Lindell Weaver MD, of Intermountain Medical Center, Murray, Utah. Fink DL8 multipurpose chamber, Fink Engineering, Melbourne, Australia.
and/or support personnel); the chamber is pressurized with compressed air while the patients breathe near 100% oxygen via masks, head hoods, or endotracheal tubes. In a Class B system, the entire chamber is pressurized with near 100% oxygen and the patient breathes the ambient chamber oxygen directly. It is important to note that Class B systems can be and are pressurized with compressed air while the patients breathe near 100% oxygen via masks, head hoods, or endotracheal tubes.

According to the UHMS definition and the determination of The Centers for Medicare and Medicaid Services (CMS) and other third party carriers, breathing medical grade 100% oxygen at 1 atmosphere of pressure or exposing isolated parts of the body to 100% oxygen does not constitute HBO\textsubscript{2} therapy. The patient must receive the oxygen by inhalation within a pressurized chamber. Current information indicates that pressurization should be to 1.4 ATA (141.86 kPa) or higher.

The literature of HBO\textsubscript{2} treatment began appearing in the 1930s as navies and universities around the world began studies in oxygen breathing at elevated pressures as a way to more safely decompress divers and to treat decompression sickness and arterial gas embolism. During the 1940s, HBO\textsubscript{2} was incorporated in standard treatment tables of the U.S. Navy. Extensive research on oxygen toxicity was undertaken to establish safe limits, overall safety, and medical and physiologic aspects of the compressed gas environment. These efforts led to a vast body of literature which underpins modern HBO\textsubscript{2} therapy.

In recognition of the need for meticulous scrutiny of emerging clinical applications of HBO\textsubscript{2}, the UHMS established the Hyperbaric Oxygen Therapy Committee in 1976. The committee was charged with the responsibility of continuously reviewing research and clinical data and rendering recommendations regarding clinical efficacy and safety of HBO\textsubscript{2}. To achieve this goal, the multispecialty committee is comprised of practitioners and scientific investigators in the fields of internal medicine, infectious diseases, pharmacology, emergency medicine, general surgery, orthopedic surgery, trauma surgery, thoracic surgery, otolaryngology, oral and maxillofacial surgery, anesthesiology, pulmonology, critical care, radiation oncology, and aerospace medicine.

Since 1976, the committee has met annually to review research and clinical data. From the twenty-eight indications for which third party reimbursement was recommended in the 1976 and 1979 reports, the number of approved indications has been refined to fourteen in the current report. These indications are those for which \textit{in vitro} and \textit{in vivo} pre-clinical research data as well as extensive positive clinical experience and study have become convincing.
Evidence considered by the committee includes sound physiologic rationale; in vivo or in vitro studies that demonstrate effectiveness; controlled animal studies; prospective controlled clinical studies; and extensive clinical experience from multiple, recognized hyperbaric medicine centers.

The committee requires that experimental and clinical evidence submitted for the efficacy of HBO₂ treatment for a disorder be at least as convincing as that for any other currently accepted treatment modality for that disorder. Studies in progress will continue to clarify mechanisms of action, optimal oxygen dosage, duration of exposure times, frequency of treatments, and patient selection criteria. The committee recommends third party reimbursement of HBO₂ therapy for the disorders included in the accepted conditions category. Currently, most insurance carriers have established HBO₂ reimbursement policies.

The committee also reviews cost effectiveness and has established guidelines for each entity. Results show that, in addition to its clinical efficacy, HBO₂ therapy yields direct cost savings by successfully resolving a high percentage of difficult and expensive disorders, thereby minimizing prolonged hospitalization. However, the committee recommends that each individual hyperbaric facility, whether monoplace or multiplace, establish its own charges consistent with the actual local costs of providing such service.

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III. Utilization Review for Hyperbaric Oxygen Therapy
A utilization review section is presented for each approved HBO₂ indication. It is recommended that utilization review be obtained if the number of HBO₂ treatments is to exceed the recommended number of treatments for that indication. Such review should involve discussion of the clinical case with another qualified hyperbaric medicine physician from an outside institution. If that individual agrees that additional HBO₂ therapy is warranted, treatment may exceed the usually prescribed number of treatments.

IV. Acceptance (Addition) of New Indications for Hyperbaric Oxygen Therapy
New indications for HBO₂ therapy are considered for acceptance at the meeting of the Hyperbaric Oxygen Therapy Committee during the annual meeting of the Undersea and Hyperbaric Medical Society. This consideration can be initiated from within the committee itself or may result in response to a written request by a non-committee member. When a new indication is considered for acceptance, a position paper is written. The information must summarize the in vitro, in vivo, and clinical aspects of the new indication for HBO₂ therapy. Two members of the Hyperbaric Oxygen Committee review the position paper and each writes a critique. The position paper and critiques are presented to the Hyperbaric Oxygen Committee. A consensus of the Hyperbaric Oxygen Committee is required for recommending the indication be moved into the approved category. If the committee determines that a new condition merits approval, it makes this recommendation to the executive committee of the Society which ultimately votes to approve or disapprove the new indication.
CHAPTER 1
AIR OR GAS EMBOLISM

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CHAPTER 2A
ARTERIAL INSUFFICIENCIES: CENTRAL RETINAL ARTERY OCCLUSION

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CHAPTER 2B
ARTERIAL INSUFFICIENCES: ENHANCEMENT OF HEALING IN SELECTED PROBLEM WOUNDS

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CHAPTER 3
CARBON MONOXIDE POISONING

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COMPROMISED GRAFTS AND FLAPS

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CHAPTER 6
CRUSH INJURIES AND SKELETAL MUSCLE-COMPARTMENT SYNDROMES

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CHAPTER 7
DECOMPRESSION SICKNESS

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CHAPTER 8
DELAYED RADIATION INJURIES (SOFT TISSUE AND BONY NECROSIS)

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CHAPTER 9
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CHAPTER 10
INTRACRANIAL ABSCESS

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CHAPTER 11
NECROTIZING SOFT TISSUE INFECTIONS

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CHAPTER 13
SEVERE ANEMIA

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CHAPTER 14
THERMAL BURNS

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CHAPTER 15
MECHANISMS OF ACTION

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CHAPTER 16
SIDE EFFECTS

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References


CHAPTER 17
HYPERBARIC OXYGEN PRETREATMENT AND PRECONDITIONING

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References


CHAPTER 18
RANDOMIZED CONTROLLED TRIALS IN DIVING AND HYPERBARIC MEDICINE

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References


**APPENDIX 1: Clinical trials in hyperbaric medicine**

*This list includes abstracts when there has been no more complete report.*

**CARBON MONOXIDE POISONING**


**CRUSH INJURY**


**GRAFTS AND FLAPS**


**TISSUE INJURY DUE TO RADIATION**


**WOUND HEALING**


ACUTE MYOCARDIAL ISCHEMIA AND CARDIAC SURGERY


ACUTE THERMAL BURNS


TRAUMATIC BRAIN INJURY


STROKE


COGNITIVE PERFORMANCE AND PSYCHOLOGY


CEREBRAL PALSY


HEADACHE


MULTIPLE SCLEROSIS


**ENHANCEMENT OF RADIOTHERAPY**


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CHAPTER 19
REGULATORY CONSIDERATIONS FOR A TRAUMATIC BRAIN INJURY (TBI)

INDICATION
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References

1. CFR Title 21 Part 312. Investigational New Drug Application.

2. CFR Title 21 Part 812. Investigational Device Exemptions.


CHAPTER 20
HYPERBARIC OXYGEN (HBO₂) FOR POST-CONCUSSIVE SYNDROME/CHRONIC TBI: PRODUCT SUMMARY

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