

**NCA Tracking Sheet for Hyperbaric Oxygen Therapy for Hypoxic Wounds and Diabetic Wounds of the Lower Extremities (CAG-00060N)**

<http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=37>

**Issue** Hyperbaric Oxygen (HBO) is a mode of therapy in which the patient breathes 100% oxygen at pressures greater than normal atmospheric (sea level) pressure. Adjunctive HBO therapy (HBOT) is used extensively in the management of a variety of disorders refractory to standard medical and surgical care. There are presently fourteen covered conditions listed in the Coverage Issues Manual (CIM). The Centers for Medicare & Medicaid Services (CMS) is being asked to evaluate whether the current literature supports expanding coverage to include the use of HBOT in hypoxic wounds and, more specifically, the treatment of diabetic wounds in the lower extremities.

Wounds such as gas gangrene, progressive necrotizing infections and chronic refractory osteomyelitis may not be considered hypoxic but rather oxygen responsive. We are also evaluating just how these wounds might benefit from treatment with HBO.

Finally, we will also address the need for physician supervision and/or physician credentialing.

**National Coverage Determination(s)** 35-10

**Benefit Category** Outpatient Hospital Services Incident to a Physician's Service, Physicians' Services

**Requestor Name(s)** Undersea & Hyperbaric Medical Society; American College of Hyperbaric Medicine; International Hyperbaric Medical Association

**Formal Request Accepted and Review Initiated \*** 11/29/2000

**Public Comment Date** 12/29/2000

**Expected Completion Date for Review of NCD Request** 7/27/2002

**Decision Memo Released** 8/30/2002

**Lead Medical Officer(s)** Ronald Dei Cas, M.D.

**Lead Analyst(s)**

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**Actions Taken**

October 6, 2000 Receipt and review of package from requestors.

November 28, 2000 Meeting with the requestors to obtain additional information.

November 29, 2000 Acceptance of formal request.

February 6, 2001 Conference call with Hyperbaric Medicine Shock Trauma Center University of Maryland

February 15, 2001 Referral to AHRQ for a technology assessment. Draft questions to be considered by the investigators:

- Is there sufficient objective evidence that the use of HBO, as adjunctive therapy to standard wound care, aids in wound healing for the following:
  - a. chronic refractory wounds
  - b. wound conditions covered under current Medicare policy
- At what point in treatment should HBO therapy be introduced?
- What other treatment modalities must be employed along with HBO therapy in order to maximize therapeutic benefits?
- Are there useful criteria to determine when an individual is likely to benefit from HBO therapy or when an individual will be non-responsive to HBO therapy?
- Are there absolute contraindications when considering HBO therapy in monoplace or multiplace chambers?

July 10, 2001 Decision was made at a regularly scheduled meeting with AHRQ to expand the scope of the subject matter into wound classification. The following question was added to the draft questions above.

Results of the technology assessment due October 15.

- Wounds are generally classified based on diagnosis. Could wounds be classified based on a criterion such as the level of

"hypoxia" rather than diagnostic specific (such as diabetic)?

- November 29, 2001 Received final Technology Assessment from AHRQ. CMS has 60 days to issue a coverage decision. The new due date for the decision memorandum is January 22, 2002.
- January 8, 2002 Meeting with members of the Undersea & Hyperbaric Medical Society and the Hyperbaric Oxygen Therapy Association.
- January 17, 2002 On January 15, 2002, CMS received a letter from the requestors asking us to expand the original request for HBO treatment of hypoxic wounds, to include, more specifically, treatment of diabetic wounds of the lower extremities. CMS agrees to accept amendment to the original request. Work is proceeding on the decision memorandum for HBOT for hypoxic wounds. The memorandum will also address HBOT for diabetic wounds of the lower extremities. The new deadline will be 90 days after receipt of additional information from the requestor as described in their January 15 letter.
- February 11, 2002 It was reported to us, upon development of our payment rate, that the service provided included physician supervision. In October 2000 the Department of Health and Human Services Office of Inspector General (OIG) issued a report on HBOT. The OIG found that lack of physician attendance is strongly correlated with lower quality of care and inappropriate billing. In addition, training could add to the quality of care. We believe it is important to evaluate the need for physician supervision and/or physician credentialing. We will assess this issue as part of our review and request public comment. The 30 day public comment period will begin on February 14, 2002. CMS considers all public comments, and is particularly interested in clinical studies and other scientific information relevant to this issue.
- April 29, 2002 On April 15, 2002, the requestors provided additional information on the subpopulations of patients with diabetic ulcers of the lower extremities for whom HBOT would be an appropriate treatment. CMS met with the requestors on April 29, 2002 to discuss this new information. In accordance with our agreement with the requestors, the new deadline for issuing a decision memorandum will be July 27, 2002.

The decision memorandum will address HBOT in the treatment of hypoxic wounds and diabetic wounds of the lower extremities, physician credentialing, and physician supervision.

August 30,  
2002

CMS posts Decision Memorandum announcing its intent to cover the use of HBOT to treat serious diabetic ulcers of the lower extremities.