

MEDICARE (CMS) APPROVES HBOT REIMBURSEMENT FOR DIABETIC FOOT ULCERS

by
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On August 30, 2002, the Center for Medicare/Medicaid Services (CMS) formally announced a decision memorandum to issue a national coverage determination for the first new indication for HBOT in the past 18 years, diabetic foot ulcers. The decision was the result of a conjoint effort of physicians, medical societies, trade associations, and a congressional office. The lengthy process began with a meeting between CMS and Dr. Paul G. Harch of LSU School of Medicine, New Orleans, representing the International Hyperbaric Medical Association (IHMA) in June, 2001. The meeting was arranged by Dr. William Duncan of Congressman Istook's Office (R, Okla) who later presented information on the potential cost savings to the government by prevention of amputation with hyperbaric oxygen therapy. The mechanism for submission of a new coverage category was discussed and by November an application was sent to CMS on behalf of the IHMA. That application and a subsequent application from the Undersea and Hyperbaric Medical Society, were reviewed with CMS on April 30th, 2002, and a memorandum acknowledging approval of the indication was issued by CMS in September. Implementation will begin next year.

The argument for HBOT in diabetic foot ulcers was based on the data that shows a reduction in major amputation rate when HBOT is incorporated into the treatment regimen. In multiple studies HBOT treated patients experienced a significant reduction in major amputation rate. These statistics made a powerful cost-effective statement to CMS and dovetailed nicely with the failure of one component of the federal government's Healthy People 2000 Initiative. In that initiative, filed in 1990, the government targeted reduction in major amputations as a priority in reducing healthcare costs and improving the quality of Americans' health. By the end of the initiative in 2000 amputation reduction had only occurred in a small VA subset of the population at risk. Given that the bulk of major amputations occur in diabetic patients the ability of HBOT to impact this figure was highly desirable.

The amputation reduction and wound healing effects of HBOT in diabetic foot ulcers is a result of an impact on the two major risk factors for amputation, ischemia/hypoxia and polymicrobial infection. HBOT has the well known ability to oxygenate hypoxic tissue by dissolving large amounts of oxygen in plasma. The effect on ischemia occurs through HBOT induced angiogenesis which begins by the 10th to 12th treatment. Lastly, HBOT directly inhibits and even kills anaerobic bacteria. By reducing the anaerobic component of infection the body's immune defenses are able to more effectively combat the aerobic component and the overall infection.

While CMS has imposed strict guidelines on the use of HBOT in diabetic foot ulcers, HBOT can begin on the day of hospital admission. Early intervention has the greatest impact. Consult Dr. Harch at Medical Center of Louisiana New Orleans' (Charity

Hospital) Albert J. Lauro Hyperbaric Medicine Unit for further questions and literature. Copies of the scientific argument and its 129 references submitted to CMS by the IHMA are available.

CASE PRESENTATION

The patient is a 60 year old diabetic male who developed a toe infection which rapidly deteriorated, resulting in a transmetatarsal amputation of the first three toes of the left foot. One week after surgery the wound had failed to progress and formed a three cm area of central necrosis, prompting a referral for HBOT. Transcutaneous oxygen measurements showed marginal room air values which dramatically accelerated upon exposure to hyperbaric oxygen. The patient began HBOT and the wound began to granulate, contract, and eventually heal.

Picture 1, 3/21/02: One week post op. Day 1 of HBOT. Note central area of necrosis and multiple other dark areas.

Picture 2, 5/01/02: HBOT #19. Note good granulation tissue and contraction of wound.

Picture 3, 5/31/02: Two weeks after completion of HBOT (30 Rx's). Continued contraction of wound with excellent granulation tissue.

Picture 4, 7/24/02: Wound is completely closed and the patient has a functional weight-bearing foot.