Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

HYPERBARIC OXYGEN THERAPY

Its Use and Appropriateness

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EXECUTIVE SUMMARY

PURPOSE

To describe the extent and appropriateness of hyperbaric oxygen treatment (HBO2) provided to Medicare beneficiaries.

BACKGROUND

HBO2 involves giving a patient high concentrations of oxygen within a pressurized chamber. Originally developed for the treatment of decompression sickness, HBO2 is primarily an adjunctive treatment for the management of select non-healing wounds. To evaluate the extent and appropriateness of HBO2 we reviewed pertinent Health Care Financing Administration (HCFA) policies and published research, met with several interest groups representing hyperbaric physicians, analyzed Medicare claims data for HBO2 between 1995 and 1998, conducted medical review of HBO2 claims for a stratified sample of beneficiaries, surveyed a sample of facilities with HBO2 chambers, and surveyed contractor medical directors.

FINDINGS

$14.2 Million (of the $49.9 million allowed charges for outpatient hospitals and physicians) Was Paid in Error for Hyperbaric Treatments

Nearly 32 percent of beneficiaries received treatments for either non-covered conditions (22.4 percent, $10.5 million) or documentation did not adequately support HBO2 treatments (9.2 percent, $3.7 million). While medical review would be necessary to identify most of these overpayments, some could have been detected had contractors utilized appropriate computer claims processing diagnoses edits.

An Additional $4.9 Million Was Paid for Treatments Deemed to Be Excessive

Eleven percent of beneficiaries were treated for appropriate indications, but received more treatments than were considered medically necessary by our physician reviewers. The excessive treatments represent $4.9 million paid for potentially ineffective procedures.

Lack of Testing and Treatment Monitoring Raise Quality of Care Concerns

Of the 68 percent of beneficiaries treated for covered conditions, 37 percent received questionable quality care with respect to either lack of appropriate testing prior to initiation of treatment or insufficient progress documented to justify continuation of therapy. The treatments with suspect quality account for as much as $11.1 million in payments. Additionally, our medical reviewers determined that more than 25 percent of beneficiaries had no documented physician oversight of their treatments; and almost twice

that many (44 percent) did not have a physician in attendance at their treatments. While attendance is not specifically required, our medical review showed a correlation between certain quality of care factors and physician attendance.

The Health Care Financing Administration's Guidance Is Limited

The guidance provided by the Health Care Financing Administration (HCFA) has been limited only to specifying covered disease conditions. As a result, carriers and intermediaries have varied payment guidelines (e.g., physician attendance, credentialing requirements), medical review procedures (i.e., use of diagnosis edits and post-payment review policies), and documentation requirements. While practice protocols and standards of care have been proposed by the HBO2 industry, HCFA has not incorporated either into its coverage policy.

Questions Over Appropriate Usage Along With a Potential for Expansion Increase the Risks Related to the Vulnerabilities Found

Although HBO2 has been a covered treatment option for many years, some questions still remain about its appropriate place in the context of wound-care. A recent assessment, performed in 1999 by the Blue Cross and Blue Shield Association, showed that some of the Medicare-covered indications do not have sufficient published evidence to determine that HBO2 is beneficial; however, this same study also documented evidence to support two conditions not specifically covered (chronic non-healing wounds and thermal burns).

Questions of appropriate usage are magnified by the expense of the treatment. Total costs for outpatient HBO2 treatments and physician supervision average between $7,000 and $12,000 with extremes exceeding $100,000. Currently, the highest rates of use are in Colorado and the southern coastal states of Texas, Louisiana, and Mississippi. If other states had the same utilization as Texas, total reimbursement would increase five-fold. While this expansion is possible, recent and proposed changes or clarifications in Medicare coverage (e.g., non-coverage of preparation for a graft not previously compromised) and reimbursement (outpatient prospective payment and physician fee schedule reductions) may curtail expansion.

RECOMMENDATIONS

To address concerns raised in this report, we recommend that the Health Care Financing Administration:

- Initiate its national coverage decision process for HBO2.
- Improve policy guidance (e.g., practice guidelines and physician attendance policy).
- Improve oversight by requiring contractors to initiate edits and consistent medical review procedures, and by exploring the establishment of a registry of facilities and/or physicians providing HBO2.

AGENCY COMMENTS

The HCFA generally concurs with our recommendations, and reports several on-going efforts to address concerns raised in this report (e.g., reviewing coverage policy and alerting carriers to vulnerabilities associated with this procedure).

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INTRODUCTION

PURPOSE

To describe the extent and appropriateness of hyperbaric oxygen treatment (HBO2) provided to Medicare beneficiaries.

BACKGROUND

Hyperbaric Oxygen Therapy

Hyperbaric oxygen therapy (HBO2) provides a therapeutic dose of oxygen by creating a pressurized environment in which patients intermittently breathe 100 percent oxygen.[1] This procedure was originally developed for the treatment of decompression sickness; but the primary usage in the United States currently is for wound care. Although the mechanisms are not firmly established in scientific literature, most agree that hyperbaric oxygen therapy serves four primary functions. First, it increases the concentration of dissolved oxygen in the blood, which enhances perfusion. Second, it stimulates the formation of a collagen matrix so that new blood vessels may develop. Third, it replaces inert gas in the bloodstream with oxygen, which is then metabolized by the body; and finally, it works as a bactericide. The proposed biological and chemical benefits of HBO2 are further described in Appendix A.

The HCFA has established fourteen conditions in its Coverage Instruction Manual (CIM) section 35-10 for which hyperbaric therapy is reimbursable. For additional information on the fourteen conditions, see Appendices B and C. The indications include:

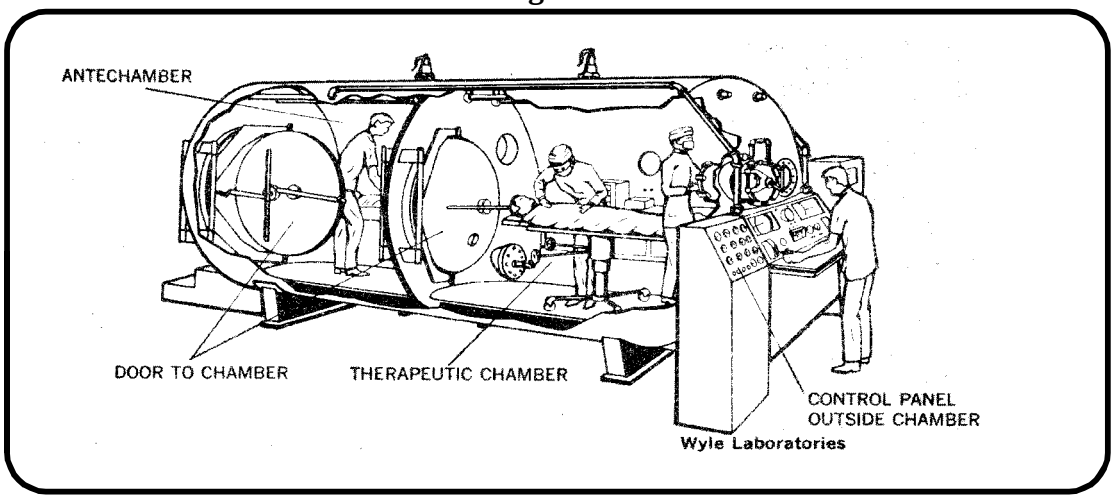
(1) Acute carbon monoxide intoxication
(2) Decompression illness
(3) Gas embolism
(4) Gas gangrene
(5) Acute traumatic peripheral ischemia
(6) Crush injuries
(7) Progressive necrotizing infections
(8) Acute peripheral arterial insufficiency
(9) Preparation and preservation of compromised skin grafts
(10) Chronic refractory osteomyelitis
(11) Osteoradionecrosis (ORN)
(12) Soft tissue radionecrosis (STRN)
(13) Cyanide poisoning
(14) Actinomycosis

The standard definition of hyperbaric oxygen therapy is intermittent 100% oxygen breathing at greater than one absolute atmospheric pressure (1 ATA); however, the

Undersea and Hyperbaric Medical Society (UHMS) reports that the pressurization should be 1.4 ATA or higher.[2] Each treatment (or "dive", an analogy relating to the pressurization) is generally between 60 and 120 minutes in length[3] ; and each patient will generally receive between 10 and 60 total sessions throughout the course of therapy.

The delivery system for this therapy may be in the form of a monoplace or a multiplace chamber. A monoplace chamber is designed for a single patient to lie in the supine position. The entire chamber is filled with oxygen for the duration of the treatment. The larger multiplace system (See Figure 1) is designed to accommodate between two and twelve patients comfortably and in a variety of positions. It often has an additional compartment for attendants to go in and out of the chamber without interrupting treatments; however, in some cases the attendant may spend the duration of the treatment with a patient. In this type of chamber, oxygen is administered through a mask or head tent during the procedure. Topical and extremity hyperbaric units describe a third class of chamber, but this class is not considered an acceptable substitute for the full body chamber and is not covered by Medicare.

Figure 1



The literature states that the most common side effects are middle ear barotrauma and claustrophobia, which occur in 2 percent of treatments. Other mild side effects include sinus squeeze, serous otitis, reversible progressive myopia, and in about 1 per 10,000 treatments, pulmonary and neurologic manifestations of oxygen poisoning.[4] Additional concerns have to do with safety related to the risk of fire created by the use of compressed oxygen.

Medicare Payments

Medicare allowed charges of approximately $76 million dollars ($47 million paid) for HBO2 in 1998 for 15,687 beneficiaries. Outpatient reimbursement was $35 million for 6,734 beneficiaries, physicians received $18 million for 7,282 beneficiaries, approximately

$19 million was associated with a hospital stay for 8,916 beneficiaries, and nearly $5 million was allowed as part of a skilled nursing facility stay for 1,408 beneficiaries.[5]

HBO2 treatments generally involve a facility charge and often a charge by a physician for supervision. Procedure code 99183 is billed for physician supervision and revenue center 413 includes facility charges for HBO2. Facility reimbursement is typically included as part of the prospective payment's diagnosis related group (DRG) payment if provided during an inpatient
hospital stay or cost-based if provided by an outpatient department. Physician reimbursement is based on a fee schedule and was approximately $140 in 1998. In contrast, cost-based outpatient reimbursement varies considerably from hospital to hospital. Cost-based reimbursement is currently being replaced with a prospective payment system for these services.

METHODOLOGY

To evaluate the extent and appropriateness of HBO2 we reviewed pertinent HCFA policies, met with several interest groups representing hyperbaric physicians, analyzed four years of Medicare payments, conducted medical review on a stratified sample of beneficiaries, surveyed a sample of facilities with HBO2 chambers, and surveyed contractor medical directors.

Medicare Payment Data

We identified all Medicare beneficiaries with hyperbaric treatments paid by Medicare between 1995 and 1998. Identification of a hyperbaric procedure was based on the American Medical Association's (AMA) CPT code 99183 (hyperbaric oxygen treatment) or facility revenue center code 413 (hyperbaric). We then extracted all payments maintained in HCFA's National Claims History (NCH), whether paid by a carrier (physician claims) or an intermediary (hospital inpatient, hospital outpatient, or skilled nursing facility claims). This data was then utilized in sample selection, provider profiling, and trending (among states and over years).

Sample Selection

Sampling was done by beneficiary with stratification based on overall payments for the entire duration of HBO2 treatment. Any beneficiary having HBO2 payments during a one year period (July 1, 1997 through July 1, 1998) represented the universe. Stratification was as follows:

Sample Stratification		
Strata *(Allowed Charges for HBO2 over entire course of treatment)*	Population	Sample Size
$100 to $5,000	4962	95
$5,001 to $10,000	2165	95
$10,001 to $20,000	1661	95
$20,001 to $100,000	622	95
Over $100,000	15	15
Beneficiaries with Physician or Outpatient HBO2 Payments	9,425	395*

**Sample reduced to 378 because of facility non-response.*

We limited strata payment calculations to *outpatient facility payments and physician payments*. Hospital inpatient services were excluded because reimbursement is based on a prospective payment system. Since the receipt of HBO2 while in the hospital was unlikely to affect the diagnosis related group (DRG) or admission, no overpayments to the facility would result from unnecessary treatment.

Medical Record Request

For each beneficiary sampled, the complete patient's medical history was requested from the point HBO2 treatments began to the point they stopped. In most cases, records were provided by the hospital where services were provided; however, in some cases, the physician provided additional information. We requested:

1. History and physical,
2. Substantiation of diagnosis for hyperbarics (e.g. lab work; photographs; operative notes; initial consult for hyperbarics; and, physician's evaluations),
3. Substantiation of hyperbaric treatment (e.g. treatment logs; physician progress notes; and, technician progress notes),
4. Substantiation of medical necessity for hyperbarics (e.g. progress notes and evaluations), and
5. Discharge summary.

Medical Record Review Process

Because of the specialized nature of hyperbarics and the need for reviewers with knowledge and expertise in hyperbarics, we contracted with four physicians who currently practice in the field and are experienced in wound management. These physicians are involved in a variety of relevant activities such as the following:

- Used as a medical reviewer for the local Medicare contractor,
- Contribute to the medical literature through journal articles,
- Actively involved in HBO2 associations (e.g., Undersea Hyperbaric Oxygen Society (UHMS)).

We developed a detailed medical review protocol which we refined with the assistance of the physician reviewers. The review protocol assessed (1) medical necessity and appropriateness, (2) adherence to Medicare coverage policy, (3) utilization patterns, (4) documentation, and (5) outcome. All reviews and medical appropriateness decisions were made by the medical reviewers.

Contractor Medical Director Survey

A brief survey was sent to each carrier and intermediary medical director asking questions about local HBO2 payment experience and policy (68 of the 74 medical directors responded). Individual perceptions of the efficacy of HBO2 were also obtained.

Facility Survey

Each facility treating beneficiaries in our sample was identified and sent a survey along with the request for medical records (211 of the 217 facilities responded). Facilities were asked to provide information about the type of chamber used and the qualifications of the staff.

Statistical Analysis

Chi-square and Cochran Mantel-Haenszel statistics, percentage estimates and corresponding 95 percent confidence intervals for key medical review data were computed using the computer program Sudaan. Sudaan is a statistical analysis program with appropriate standard statistical formulas for calculating correct standard errors for complex sampling using stratification.

Non-Response Analysis. A non-response analysis was conducted for the seventeen facilities that failed to provide records for the medical review. Thirteen of the facilities (76%) did complete the facility survey describing practices and characteristics of the hyperbaric department. No significant differences were found between the responding and non-responding facilities with the exception that non-responding facilities were more likely to use a multiplace chamber (p=.04) and employ at least one full-time physician (p=.06).

This inspection was conducted in accordance with the *Quality Standards for Inspections* Issued by the President's Council on Integrity and Efficiency.

FINDINGS

Questions persist concerning the appropriate usage of hyperbaric oxygen therapy

For years, hyperbaric oxygen therapy has been considered a controversial procedure because of a lack of rigorous scientific evidence demonstrating the efficacy of its use for many of the conditions Medicare covers. This was the conclusion, in 1995, by the Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ).[6] Their review criticized available research studies for having poor study design(s), non-standardized protocols and poor patient selection" which caused "equivocal and conflicting conclusions concerning [HBO2's] efficacy." In response to these criticisms, HBO2 interest groups countered that small sample size and lack of control groups were research problems inherent to the conditions being treated. Consequently, AHRQ's review discounted much of the most compelling evidence as a result of methodological issues.

Since AHRQ's review, the body of research supporting HBO2 has continued to grow, with some studies achieving adequate research standards (i.e., appropriate control groups, adequate sample size, an appropriately defined and homogeneous patient population, a well described treatment regimen, valid health outcome measures, and publication of results in a full length, peer-reviewed journal article). While the research has yet to fully prove the efficacy of all the currently approved conditions, a recent (1999) review by the Blue Cross and Blue Shield Association's Technology Evaluation Center for a select number of medical conditions found adequate scientific evidence to support acute traumatic peripheral ischemias, clostridial myonecrosis, and a few conditions not specifically covered by Medicare, such as chronic non-healing wounds[7] and burns.[8] Although this review found evidence of efficacy for these conditions, adequate evidence was not found to validate the efficacy of several conditions Medicare currently covers: compromised skin grafts, chronic refractory osteomyelitis, and necrotizing soft-tissue infections. The results support the claim that hyperbarics is a beneficial treatment; however, Medicare may not cover the appropriate conditions. Furthermore, hyperbarics may not be the most cost-effective treatment option for some patients and conditions.

Carrier and intermediary medical directors support the use of HBO2, but vary in opinion on the extent of covered indications. While over half of all carrier and intermediary medical directors responding to our survey said hyperbaric therapy is beneficial for all of the currently covered conditions, one third still believe that hyperbaric coverage is too broad.

Outside the United States, HBO2 is viewed with less conservatism. International medical communities cite as many as 20 classes of indications, relating to 66 specific conditions, for HBO2 (See Appendix E). This is considerably more than the 14 indications approved by the HCFA.

Hyperbarics is most commonly used to treat wound related problems

The most commonly treated indications for Medicare beneficiaries are arterial insufficiency, effects of radiation and compromised skin grafts. The following figure (Figure 2) indicates the breakdown of primary treatment indications found in the medical review sample.[9]

Figure 2
CIM 35-10 Indications for Treatment
(% of beneficiaries)

Acute Peripheral Arterial Insufficiency	20.9%
Effects of Radiation (ORN and STRN)	15.1%
Preparation & Preservation of Skin Grafts	15.0%
Chronic Refractory Osteomyelitis	8.6%
Progressive Necrotizing Infections	4.0%
Gas Gangrene	1.3%
Decompression Sickness	0.8%
Carbon Monoxide Poisoning	0.6%
Acute Traumatic Peripheral Ischemia	0.2%
Non-covered primary indications[10]	33.5%

Costs per individual are very high

The number of beneficiaries actually receiving hyperbarics remains relatively small, but the costs per beneficiary can be very high. The average total allowed charge per treatment in 1998 was approximately $405 ($140 for physician supervision and $265 for outpatient services). Coupled with the relatively high average number of treatments per individual (29), this results in an average allowed therapy cost of over $12,000 for a single patient. The top five percent of beneficiaries have considerably higher costs, ranging from $50,000 to $325,000 per individual. The hyperbaric societies contend that although the procedure is relatively expensive and benefits a very small group of individuals, hyperbaric oxygen therapy is a cost-effective means to treat candidates with select wounds and a few life-threatening medical conditions. The UHMS Committee Report (1996) states that "aside from clinical efficacy, HBO2 yields direct cost savings by successfully resolving a high percentage of difficult and expensive disorders, thereby minimizing prolonged hospitalization."

Individual outcomes vary greatly

Although our medical review did not attempt to independently evaluate the overall efficacy of HBO2, the benefits of hyperbarics, as evaluated by our medical review team, ranged from saving lives to no benefit at all. While a few are believed to have benefitted

to the extent that either life or limb was saved (0.7 percent), thirteen percent of beneficiaries showed no improvement of their medical condition after treatment with HBO2. The treatment may also be considered burdensome to the beneficiary, for they are financially responsible for at least 20 percent of the cost of therapy; and according to our review, 18 percent demonstrated side effects as a result of the HBO2.[4] Furthermore, there is no way to determine if those who do benefit would have seen improvement without the treatment or with other aggressive wound care. However, to acknowledge the risks, costs and variable outcomes does not necessarily disparage this procedure. Hyperbaric therapy is generally reserved as a last resort, when other treatment options are exhausted. The population targeted is generally elderly and very ill. The average age of a hyperbaric Medicare patient is 70. At least 45 percent are diabetic; and almost 40 percent have some form of heart disease. It also appears that about 18 percent are deceased within two years after treatment. Hyperbarics is often an end of life procedure and may provide a reprieve from painful non-healing wounds; and in some cases, it is credited with saving lives.

Potential for expansion exists within the hyperbaric industry

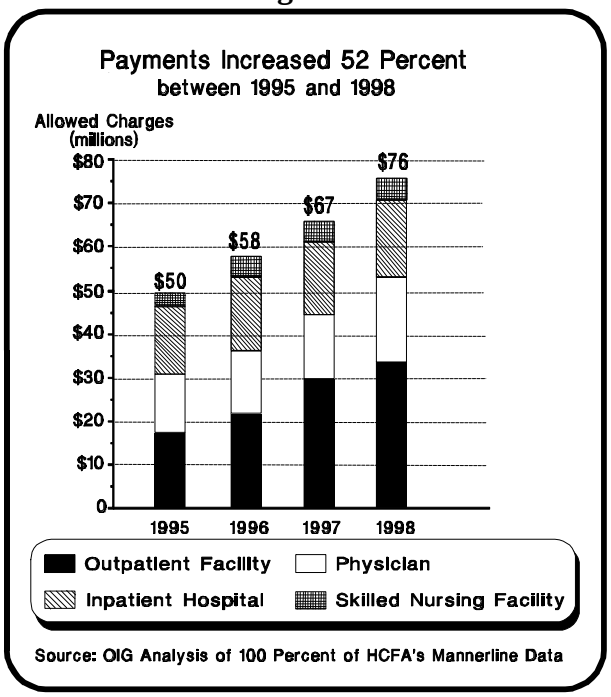
Medicare Payments and Providers Steadily Increased From 1995 to 1998

In 1998, allowed charges were approximately $76 million for 15,687 beneficiaries. Charges were distributed between physicians (24 percent), hospitals (70 percent), and skilled nursing facilities (6 percent). Between 1995 and 1998, charges increased by 52 percent (*not adjusting for inflation*) while the total number of Medicare beneficiaries treated increased by only 27 percent. (See Figure 3.)

The increases in payments and beneficiaries were outpaced by even larger increases in the number of providers of HBO2 during this same period. For example, the number of hospitals billing outpatient HBO2 increased by 122 percent (from 232 facilities to 514), while the number of physicians billing HBO2 procedures increased 64 percent (from 642 to 1053).

The increases in billing and providers of HBO2 parallel overall growth in the wound care market and reflect increased access to affordable chambers. The Florida-based American Academy estimated that in 1998 the market for hyperbaric chambers was $1.74 billion and is expected to grow to

Figure 3



$2.57 billion by 2002.[11] The dramatic rise in the wound care market has created an attractive opportunity for medical equipment suppliers who are making chambers available at costs of less than $100,000 or through lease arrangements.

Utilization Varies Between Geographic Regions

The highest rates of per capita use of HBO2 are in Colorado and the gulf states of Texas, Louisiana, and Mississippi. By far, Texas is the state with the highest number of treatments and total billing; total allowed charges were over $21 million in 1998, nearly three times the charges of any other state. The disproportionate use of HBO2 is most likely a result of geographic differences in exposure to hyperbarics in medical schools, professional environments, incidence of diabetes, and access to chambers. Since chambers were originally developed to treat decompression illness, it is not surprising that chambers would be located in coastal areas, particularly areas proximate to deep sea oil wells. As researchers discovered other uses for HBO2 (i.e., wound care), additional chambers were installed in those areas. While chambers can be found in most states, variation in billing for HBO2 between states and the limited numbers of chambers in many states suggests an opportunity for expansion. Whether hyperbaric therapy is under-utilized in most states or over-utilized in a few is not certain; however, if utilization were to expand across the country to levels similar to Texas, HBO2 reimbursements would increase nearly five-fold. Additionally, if HBO2 were found to be beneficial for other disease conditions (e.g., diabetic foot or non-healing wounds) and consequently added to Medicare's coverage policy, use of HBO2 could substantially increase in every state.

$14.2 Million was paid in error for hyperbaric treatments (of the $49.9 million allowed charges for outpatient hospitals and physicians)

HBO2 treatments for 32 percent of beneficiaries were identified by our medical review team as inappropriate. Either beneficiaries received treatments for non-covered conditions (22.4 percent of beneficiaries, $10.5 million) or documentation was not sufficient to support HBO2 treatments (9.2 percent, $3.7 million). This projects to total allowed charges for HBO2 billed in error by physicians and outpatient hospitals of $14.2 million in the sample year (July 1, 1997 to July 1, 1998). (See Appendix D.) This represents approximately 28 percent of total payments paid to outpatient facilities and physicians during the sample year. While medical review would be necessary to identify most of these overpayments, some could have been detected had contractors utilized appropriate computer claims processing diagnosis edits.

The discrepancy between indications recommended by the hyperbaric community and those acceptable for Medicare reimbursement contribute to inappropriate billing

Discrepancy exists between the treatment indications approved for Medicare reimbursement and indications considered appropriate by the hyperbaric medical societies (UHMS and ACHM). The most prominent examples are the extension of treatment to the

diabetic foot and to thermal burns. Appendix E - "*Recommended Usage of HBO2 by HCFA and Interest Groups*", lists potential indications for HBO2 including HCFA coverage, as well as the recommendations of the two medical societies, plus one set of international guidelines. The treatment indications for which there are discrepancies between HCFA coverage and the domestic interest group guidance are bolded.

Many facilities rely on information provided by these groups to develop practice standards. The differing recommendations of these authorities can create confusion. The failure of some providers to recognize the difference between interest group suggestions and HCFA's formal payment policies may lead to inappropriate billing. One example described by a representative of UHMS regards the controversy surrounding non-healing wounds.[12] "Reputable hyperbaric physicians around the country have tried to treat [patients with non-covered hypoxic wounds] on the basis of good experimental and clinical evidence justifying their treatment plan in terms of arterial insufficiency and acute ischemia as the only available means to describe the aforementioned hypoxic wound." This comment alludes to the parallel between covered and un-covered conditions[13]; and the fact that physicians will sway their interpretation of diagnosis codes to align treatment practices with their own medical judgements. Difficulty discerning covered from uncovered conditions combined with the inclination of many physicians to follow their own medical judgement (as influenced by the medical societies) rather than payment guidelines sometimes result in inappropriate Medicare claims.

Diagnosis codes are sometimes used inappropriately to obtain reimbursement for uncovered indications

Although the guidelines specifically describe fourteen indications for which hyperbaric treatment is reimbursable by Medicare, some providers have taken great latitude in how they interpret those conditions, while others appear to deliberately use inaccurate ICD-9 codes to bypass carrier and intermediary edits. Our reviewers found 13 percent of beneficiaries had diagnoses listed on their claims that misrepresented their true medical condition. For example, of the hyperbaric charts reviewed using the diagnosis code gas gangrene (n=24), only three were found to have "wet" (a.k.a. gas) gangrene (the only type of gangrene covered). Ten of the remaining 21 charts showed a primary indication of "dry" gangrene, an indication not covered by CIM 35-10 in and of itself. The reviewers also determined that treatment courses in accordance with the CIM 35-10 guidelines tended to have billing diagnoses that accurately described the beneficiary's condition; but, of treatment courses that did not comply with the CIM 35-10 guidelines, over half had a billed diagnosis that described a secondary or tertiary indication or was deemed to be erroneous.[14] This relationship ($p<.001$) suggests that diagnosis codes are, at times, selected for the purpose of bypassing the carrier and intermediary edits used to flag potentially inappropriate treatments.

The problems related to diagnosis codes are exacerbated by the absence of ICD-9 codes specific to some of the covered conditions (e.g., Meleney's ulcer and Arterial Insufficiency). Contractors, in their interpretation of the 35-10 guidelines to system edits, are forced to accept loosely related diagnoses on claims to justify medical necessity. The slack created by the interpretation allows physicians to treat non-covered indications

without falsifying the diagnosis. A few billing diagnoses, identified by the medical review, are frequently associated with non-compliance of the 35-10 guidelines. Claims with a billing diagnosis of "chronic ulcer" were found to be out of compliance almost two-thirds of the time ($p<.001$); and, those with a billing diagnosis of "pyoderma" were out of compliance in almost half of the cases ($p<.01$).[15]

Some Providers did not provide sufficient documentation to justify Medicare reimbursement

Billing errors and inadequate documentation account for 9 percent of beneficiaries treated with HBO2. In most cases, sufficient documentation was simply not provided. An on-site review at one of the hospitals failing to provide records resulted in recoupment action and a referral for a fraud investigation. While treatments may have been provided, the facility was unable to provide the intermediary with adequate documentation (e.g., treatment logs) in nearly all of the cases requested. In addition to documentation problems, three charts in the sample were counted as inappropriate because they billed Medicare for topical hyperbaric oxygen therapy - a procedure explicitly excluded in the reimbursement guidelines. Five charts used the 99183 code or the revenue center 413 for related procedures other than HBO2 (e.g., basic wound care). Medical records for three charts showed that the beneficiary for whom claims were received was never treated with hyperbarics. The remainder of this group (12 charts) provided documentation, but it was not sufficient to complete the reviews.

An additional $4.9 million was paid for treatments deemed to be excessive

Eleven percent of beneficiaries were treated for appropriate indications, but received a greater number of treatments than were considered medically necessary by our physician reviewers. The excessive treatments represent $4.9 million paid for potentially ineffective procedures. (See Appendix D.) The only controls concerning the length of therapy are a requirement that courses of therapy extending beyond two months be reviewed and that treatments should be medically necessary.

Our review raised several quality of care concerns

Another $11.1 million was spent on treatments of questionable quality

Of the beneficiaries appropriately treated with hyperbarics, 37 percent[16] received treatments that likely did not yield the maximum benefit possible. This projects to $11.1 million spent on such treatments. We examined two proxy variables for quality of care: (1) insufficient progress to justify continuation of therapy, and (2) inappropriate or inadequate testing. Of beneficiaries treated for appropriate indications, 35 percent did not show sufficient documented progress to justify continuation of the therapy; and 15 percent did not have appropriate testing to confirm a diagnosis supporting the use of hyperbarics. (See Appendix D.) Existing Medicare guidelines do not set testing or monitoring standards; however, some of these services might be deemed medically unnecessary.

Physician attendance remains a point of contention

Two perspectives on the meaning of *'attendance'* are prominent in the hyperbaric community: (1) the physician is physically present during the entirety of the treatment and uses that time to manage the patient's overall care; and (2) physicians remain available to manage rare emergency situations. Over 75 percent of medical directors agree that physician attendance is necessary to promote either safety or quality of care or both. Fifty-six percent of facilities claim to have a physician in the same or adjacent room 100 percent of the time. In contrast, part-time physicians and those that supervise, but do not physically attend treatments, tend to be of the opinion that their purpose in attendance is not to manage the patient, but to manage emergencies.

Our review indicates physician attendance is strongly correlated with quality of care and the reduction of inappropriate billing. Almost two-thirds of medical directors do support the notion that physician attendance is necessary to achieve quality. Similarly, our medical review results supported this concept, showing a significant relationship ($p<.001$) between quality of care variables and physician attendance and between compliance with HCFA guidelines and physician attendance ($p<.001$). These relationships provide support for requiring physician attendance during all treatments. For example, 74 percent of the payments termed "inappropriate" by our reviewers did not appear to have a physician in attendance. We cannot be certain that physician attendance would have corrected all of these payments, but the strong relationship between quality and attendance suggests a potential for reducing inappropriate payments.[17]

Many facilities do not require physical physician attendance. The reviewers determined that more than 25 percent of beneficiaries had no physician oversight of their treatments; and twice that many (44 percent) did not have a physician in attendance at their treatments.[18] Self-reported data from facilities confirms that some facilities (at least 10%) never have a physician in attendance and approximately one quarter have physicians in attendance less than half of the time. Over half of the facilities surveyed stated that supervising physicians were employed part-time, if at all.

Training requirements may provide a means of promoting quality care

Some local medical review policies (LMRPs) aim at improving the quality of care by requiring physician attendance and setting qualifications or credentialling requirements for the supervising physicians. One policy implemented by Blue Cross and Blue Shield of Texas (now Trailblazers) sets such requirements. Under this policy, the supervising physician must meet the following criteria:

(1) Training, experience and privileges to manage cardiopulmonary emergencies;
(2) Training, experience and privileges to manage emergency myringotomies;
(3) Completion of a 60 hour course in hyperbaric medicine recognized by UHMS or ACHM [19]; and,
(4) Completion of 16 CME credits every two years after credentialling.

Only 41 percent of the facilities we surveyed have even one physician who meets these requirements. Facilities employing at least one full-time doctor meet the requirements more often than those that do not.[20] A recent proposal by HCFA to modify the CIM 35-10 guidelines suggested adopting requirements such as these. Although the hyperbaric societies do support training requirements, they and the American Medical Association (AMA) object to the imposition of such requirements by HCFA on the grounds that credentialling is the responsibility of hospitals or licencing boards and does not meaningfully fall under the jurisdiction of the government. However, we believe HBO2 is a service highly vulnerable to misuse (as seen by our medical review). It is also a procedure that generates little attention because a low number of patients are affected and because the total dollar amount in jeopardy is relatively small. In such a case, a national credentialing or training policy would ensure all contractors institute such requirements.

Many carriers and intermediaries play only a limited role in assuring the quality of hyperbaric care

Although the peer review organizations (PROs) may be primarily responsible for ensuring the quality of care provided in facilities, there are several ways that carriers and intermediaries could promote a higher quality of care, such as communicating new developments in medical standards highlighting differences between medical opinions and payment guidelines, and performing periodic post-pay edits to confirm that diagnostic and ancillary services are provided appropriately. From surveying the Medicare medical directors about their organization's activities promoting quality care, we found a mixed bag of approaches to quality issues. Over half report that they provide voluntary guidance upon request and use edits to confirm that diagnostic and ancillary services are provided appropriately. However, only 34 percent and 41 percent, respectively, publish standards of HBO2 care in a regular newsletter or deny claims when sub-standard care is found. Although prescriptive policies are somewhat controversial, 13 percent did report providing suggested protocols to hyperbaric facilities. Several other medical directors mentioned referring cases to the PRO, creating additional requirements (such as attendance, credentialling, or specifying appropriate settings) in their LMRPs, and one medical director stated that his carrier/intermediary performs pre-pay reviews for hyperbaric treatments.

Some carriers and intermediaries do not apply edits and appropriate medical review standards to ensure compliance with the CIM 35-10

Billing data from our sample showed evidence that carriers and intermediaries do not uniformly use edits to detect procedures billed with inappropriate diagnoses; nor is there a uniform protocol for reviewing medical records for appropriateness of indication and medical necessity after two months of treatment.[21] It appears that 23 percent of bills are paid with an inappropriate billing diagnosis (which could have been identified by a pre-payment edit). Of these, 53 percent are not in accordance with CIM 35-10 and should not have been paid. (This relationship is significant at p=.001.)[22]

Local medical review policies and implementation of system edits vary by contractor. The implications of such variation include likely differences in coding patterns and rates of inappropriate reimbursements. Further differences exist in the level of medical review employed. As an example, one intermediary only verifies that the billing diagnosis is covered (ICD-9 code is valid) and does not routinely review medical records to substantiate the authenticity of the patient's condition or question the amount charged. This limited medical review process leaves the contractor vulnerable to fraud, inappropriate utilization, and inflated charges. Our review found one hospital taking extreme advantage of these vulnerabilities. The facility routinely charged $5,500 and the contractor allowed $4,400 for each individual treatment. In contrast, most facilities average allowed charges between $250 and $300. Upon our request for the hyperbaric facility's records, they sent virtually no documentation that the treatments were even performed. At our request, post-payment review at the facility was performed by the intermediary; and consequently, $1.3 million in erroneous payments were identified and recoupment initiated. Although these problems are extreme, the lack of oversight described is not unique. For example, another intermediary reported that facilities were on the "honor system." As a result, claims were being paid for non-covered conditions such as multiple sclerosis, heart attacks, cancer, and pneumonia. (Since being contacted by the Office of Inspector General (OIG), this contractor reported it has begun using a front-end editing tool called Super Op to detect these situations.)

According to self-reported data, 42% (29/68) of medical directors confirm their institutions have no edits in place for hyperbarics. The CIM 35-10 guidelines describe at least two conditions for which edits are a feasible method of screening: (1) limiting coverage to fourteen diagnosable conditions; and, (2) requiring a review for any course of treatments extending beyond two months. Almost 60 percent of carriers and intermediaries do not have system edits for both of these conditions.[23]

Once a bill is identified as requiring a pre- or post-payment review, the mechanism can differ by carrier or intermediary. Fifteen percent of contractors self report that the process is comprised merely of reviewing diagnosis codes and nothing else. In general, approximately 60 percent of medical directors reported that they do confirm that treatments are actually provided and that those treatments are medically necessary and within HCFA's diagnosis parameters. However, the majority (72 percent) do not have medical review procedures to routinely detect over-utilization of treatments, whether hyperbaric therapy is used adjunctively (not as a primary therapy), and whether progress is monitored appropriately by a physician throughout the treatment.[24]

HCFA's guidance for this procedure is limited

The guidance provided by HCFA controls usage only by (1) limiting indications for treatment, (2) creating a provision that HBO2 must be adjunctive to primary therapy, and (3) denying coverage for topical hyperbaric oxygen therapy. The guidance may be found in Appendix B. Although these restrictions appear quite clear, in application they often become vague, and in some areas, inconsistent.[25]

Many carriers (68%) and intermediaries (54%) have no local medical review policy or payment guidelines independent of the CIM 35-10

When asked about efforts to convey the intent of CIM 35-10 to physicians providing services, over one quarter (12/44) of carrier medical directors stated they do nothing beyond relying on information within the CIM 35-10 guidelines. As one medical director expressed, "CIM 35-10 is a national coverage policy. In these cases [referencing potential misinterpretations], we feel it should be HCFA and not local contractors that clarify intent." This stand may not be the position of all contractors; but in light of the wide-spread misuse identified by the medical review analysis, one could conclude that the existing guidelines are not sufficient.

Carriers and Intermediaries vary in how they interpret and implement CIM 35-10

A comparative analysis of acceptable ICD-9 codes for four local medical review policies and HCFA's 1999 proposed revision to CIM 35-10 may be viewed in Appendix F. The table clearly shows significant variation in interpretations of the CIM 35-10 guidelines. For example, a LMRP from Transamerica of Southern California accepts only one code for arterial insufficiency (443.9 peripheral vascular disease), while HCFA's proposed interpretation of the indication arterial insufficiency included three codes very different from Southern California (444.21, 444.22, and 444.81, all for arterial embolism). The two translations into ICD-9 codes without the context of the overarching indications might lead physicians to draw very different conclusions about Medicare coverage. Further examples of interpretation problems include the extent of coverage for skin grafts, the use of the term Meleney's ulcer[26], and coverage for the Marx protocol[27].

At the time of our survey, HCFA had previously released a memo stating its interpretation of the condition "preparation and preservation of a compromised skin graft" meant that a graft must have been previously placed in order for the treatments to be reimbursable. This clarification was a response to the confusion regarding the intent of the word preparation in the term "preparation and preservation of a compromised skin graft." Our medical review demonstrated this problem. Twenty-five percent of beneficiaries treated under the guise of this indication had neither a previous compromised graft nor a graft ultimately placed (64 percent never had a previous graft failure and 44 percent did not have a graft ultimately placed). Because of the confusion related to the skin graft indication, some contractors ceased coverage of preparation of a skin graft entirely, leaving only the preservation segment of this indication. When asked, in general, if the preparation of a skin graft is a

covered condition, only 38 percent of Medicare medical directors agreed that it is covered at all (regardless of a previously compromised graft).

Another such example is the interpretation of the condition "progressive necrotizing infections". Specifically included with the indication are the terms necrotizing fasciitis and Meleney's ulcer. This creates a problem because there is no ICD-9 code describing Meleney's ulcer, a very specific condition. In the absence of an appropriate code, bills are submitted with the diagnosis codes of necrotizing fasciitis, pyoderma, and cellulitis. Pyoderma and cellulitis are very broad terms and have created a niche for billing a broad variety of ulcers that do not necessarily fit the diagnostic criteria of Meleney's ulcer. Medical director's interpretations of the over-arching indication ("progressive necrotizing infections") have ranged from a broad interpretation (including any wound with necrotic edges) to the specific classification of this indication as only applying to life-threatening emergency treatment of fasciitis.

Coverage of the condition osteoradionecrosis poses a different interpretation problem. There is no effective way to diagnose this condition until a breakdown of the bone occurs. When symptoms are observed, it is often too late to gain much benefit from HBO2. In this case, the primary usage of HBO2 is prophylactic, most frequently utilized in accordance with the Marx protocol. Although no specific exception to the Medicare policy allows preventative care, this type of procedure is representative of as much as nine percent of HBO2 beneficiaries. Moreover, almost 40 percent of medical directors state that this form of therapy is reimbursable and an additional 30 percent believe that, although it is not covered, it should be. This form of hyperbaric therapy is one of the more well-supported in scientific literature[28]; however, the conflict between these two Medicare policies has never been addressed.

Standards of care have not been incorporated into HCFA's guidance to reduce over-utilization

The number of treatments considered appropriate is not the same across indications, nor is the testing required to determine diagnoses. In 1995, the ACHM created "Preferred Practice Protocols" that, in most cases, describe diagnostic and treatment patterns specific to each indication. In addition, the 1999 revision of UHMS's "Committee Report" includes a utilization review for each indication. To date, neither these nor similar protocols have been promoted by HCFA as a method of evaluating appropriate treatment.

Many hyperbaric practices are started with little information on proper utilization or reimbursement policies. According to interviews with hyperbaric physicians, many hyperbaric units are not started by physicians. They are started by facilities which may have little knowledge of proper utilization and standards of care. This lack of knowledge is a likely cause for non-compliance with HCFA's guidelines, excessive treatments and a lower quality of care. Solicitations and contractual arrangements with hyperbaric entrepreneurs contribute to this problem. Some manufacturers will install chambers in a facility at no cost. The incentive for the manufacturer is that they receive a portion of the revenue generated by the chamber. This type of arrangement allows hospitals to institute

such facilities with no capital outlay cost (and possibly no risk). The draw from institutions seeking a chamber for profit, combined with low risk acquisition, increases the pool of potential facilities thereby increasing the variation in the rigor of practice standards and expertise of personnel. Evidence supporting this claim is anecdotal; however, the implications in terms of total billing and the degree to which billing might be inappropriate may be significant.

Many billing physicians and facilities have little HBO2 experience. Nearly half of all physicians (43 percent) and hospitals (47 percent) billing hyperbarics in 1998 treated no more than 5 Medicare beneficiaries. Half of these treated only one beneficiary. This finding raises concerns about the experience and expertise of these providers regarding current HBO2 practice protocols.

Many facilities do not independently substantiate the diagnostic basis for treatment. Our reviewers found that almost half of beneficiaries whose treatments were considered to be appropriate did not receive proper testing to confirm their diagnosis. Because hyperbaric units are considered secondary or tertiary treatment centers, documentation of diagnosis was sometimes never confirmed or even documented within the hyperbaric facility. Those records are expected to be maintained by the patients' primary physicians. In some cases, we found only an order for treatment and treatment logs. This reliance on other physicians to determine the necessity of treatment may be a contributing factor to the number of patients treated inappropriately.

An absence of documentation guidance combined with the inadequacy of medical records found in this review suggests this area needs attention. Inadequate documentation was a complicating factor in our medical review. The extent of documentation varied a great deal. In a few cases, facilities provided only a date of service, documentation that a "dive" took place and a quick note on how the patient tolerated treatment. Such records are grossly inadequate. Oxygen delivered in a pressurized environment is analogous to a drug; and considering such a comparison, the dosage should be adequately recorded along with other pertinent information. Our expectation of documentation was that each record would include:

- a history and physical,
- an assessment of the patient as a candidate for hyperbarics,
- an evaluation of medical necessity,
- a treatment plan,
- regular documentation of progress and reassessments of the treatment plan,
- and daily logs of the procedure (including ascent time, descent time, total bottom time, dose of oxygen, pressurization level (ATA), documentation of attendance, and a recording of events).

This full level of documentation was rarely provided. Only 28 percent of records reviewed showed both an adequate plan of care and adequate objective treatment measures.[29] The absence of this information, along with the previously discussed problem

that many facilities do not independently substantiate diagnoses, suggests the possibility of a systemic problem with the determination of medical necessity. In addressing this issue, we found no guidance from HCFA on the necessary level of documentation to support Medicare billing. The medical directors surveyed had differing opinions on what constitutes adequate documentation for billing. Many feel that it is the responsibility of the referring physician to maintain records supporting medical necessity (whether or not these medical directors intended on using referring the physician's records in a post-pay review varied). Other medical directors argued that it is the responsibility of the hyperbaric facility to keep sufficient documentation of the diagnosis and that the treatment is reasonable and necessary.

The role of the hyperbaric physician is unclear

The duties implicit in billing the 99183 hyperbaric code are unclear. The role of the physician has been defined by ACHM as an exhaustive list of duties to be performed before, during and after treatment. The ACHM stated that this list was produced at the express request of HCFA to describe the physician work as a component of the resource-based relative value system (RBRVS), on which the physician payment of approximately $140 is based. The list of duties described by the ACHM suggests that oversight of the wound and some routine wound care are implicit in the duties of the 99183 code for hyperbarics.[30] However, the AMA's *"Physician's Current Procedural Terminology"* since 1994 and similarly, the Federal Register in 1993 state that "E/M [Evaluation and Managment] services and/or procedures (e.g., wound debridement) provided in a hyperbaric oxygen treatment facility in conjunction with a hyperbaric oxygen therapy session should be reported separately." The absence of a document describing the duties implicit in billing the 99183 code creates a vulnerability where some physicians bill for routine services in addition to the 99183 code while others believe that the same services are included in the fee assessed for hyperbarics.

The definition of "attendance" is unclear. An additional source of confusion relates to the previously discussed concept of attendance and supervision. Many hyperbaric doctors disagree on whether a doctor can supervise a treatment without being in attendance. However, if the ACHM guidelines truly do represent the physician's responsibilities, his or her duties could not be performed without being in physical attendance for each treatment. On the other hand, some argue that this procedure is routine; and consequently, a physician might merely be available in case of emergencies, and thus, could supervise the treatments from afar. In light of these varied opinions, HCFA announced an additional code for hyperbaric oxygen treatments not requiring physician attendance (G0167) in the November 2, 1999 issue of the Federal Register. This code allows for the same payment to the physician as the 99183 code, minus the cost associated with physician work. There is some concern in the medical community that the existence of two codes will have significant implications in terms of documentation requirements. If a determination of medical necessity is required for each code, some form of triage will be necessitated. In addition, 58 percent of medical directors do not personally support the addition of the new code. For, if attendance is truly a cornerstone of quality, the additional code undermines the rationale originally implied within the 99183 code.

Recent and impending regulatory changes may affect growth

Several changes (both recently effected and proposed) to the reimbursement structure and the CIM 35-10 coverage guidelines may have an impact on the hyperbaric industry.

Coverage Guidance: On three occasions in 1999, revisions to the current CIM 35-10 have been proposed and then delayed. The most recent proposal is delayed until April 1, 2001. While HCFA contended that the proposed revisions did not make substantive changes, some hyperbaric physicians argued that the modifications would reduce coverage and impose additional requirements (such as physician attendance) that could not be met by many facilities and would consequently cause many HBO2 providers to go out of business.

Outpatient Rate: When payment rates were initially calculated by the HCFA, reimbursement was proposed at $145. (Strikingly, the beneficiary was responsible for nearly all of this amount with a coinsurance of $141.) This reimbursement rate was far short of the average costs, which ranged between $273 and $292 as calculated by the Hyperbaric Oxygen Therapy Association (HBOTA). The obvious concern within the hyperbaric community was that low reimbursement levels might cause HBO2 units to shut down or force hospitals to subsidize their costs.

In response to these concerns, the HCFA reclassified the HBO2 procedure as a "new technology" and reset the reimbursement rate at $75 per 30 minute period. The reclassification as a new technology also replaces the excessively high beneficiary coinsurance payment with the standard 20 percent. Since a typical HBO2 treatment is 90 minutes long, the new reimbursement rate is approximately $225. While still short of the industry's estimated costs, this rate appears fair, given that our analysis of 1998 payments shows half of the facilities have average charges over this amount and half are under this amount. The overall average allowed for all facilities was $265 ($605 submitted and $145 paid).

Physician Fee: Changes to the Medicare fee schedule payments for physician services are gradually decreasing the reimbursement rate from 1998 levels. Between 1998 and 2002, the practice expense relative value is expected to decrease by 60 percent (from 1.81 to 0.73). This reduction will result in a 33% reduction in current payments to approximately $100. The reduction is a result of congressionally mandated changes in the fee schedule from charge-based RVUs to resource-based RVUs. Our medical reviewers (who are currently practicing HBO2 physicians) are concerned that these reductions may discourage physicians from specializing in hyperbarics, which could further reduce access to the procedure. However, the mechanism utilized to establish fee schedules has several protections to ensure that rates are calculated fairly. These mechanisms include an appeal process through HCFA and a practice expense advisory panel of AMA representatives to advise HCFA when resource inputs are incorrect.

RECOMMENDATIONS

Our results show that a significant percentage of HBO2 is provided inappropriately. Either HBO2 should never have been used (not a covered diagnosis), excessive treatments were provided, or documentation of services was not available.

To address concerns raised in this report, we recommend that the Health Care Financing Administration:

- **Initiate its national coverage decision process for HBO2.**

  This review is requested because (1) questions persist concerning the appropriate usage of HBO2, (2) there are program integrity issues surrounding significant inappropriate payments, and (3) there are conflicting carrier and intermediary policies. Considering the overlap of HBO2 with other wound-care procedures, this review might consider HBO2 within the broad context of wound care and in terms of its relative cost-effectiveness.

- **Improve policy guidance:**

  1. Provide clear descriptions of covered conditions;

  2. Propose additional ICD-9 codes as needed to more closely parallel covered conditions;

  3. Establish a clear physician attendance policy;

  4. Consider establishing training requirements;

  5. Consider incorporating clinical standards of patient selection and treatment protocols designed with the aid of hyperbaric physicians; and,

  6. Specify medical record documentation requirements.

- **Improve oversight:**

  1. Require contractors to initiate edits and medical review procedures which insure that uncovered diagnoses are not paid and high treatment thresholds are subject to review.

  2. Explore the establishment of a registry of facilities and/or physicians providing HBO2 to improve communication and facilitate monitoring.

Agency Comments

The Health Care Financing Administration (HCFA) generally concurs with our recommendations. They expressed that their goal, as ours, is to provide beneficiaries access to effective services and to make payments for those services appropriately. We recognize HCFA's on-going efforts to improve and clarify Medicare's policy on Hyperbaric Oxygen Therapy (HBO2) such as responding to national coverage requests and issuing guidance memoranda. We also appreciate their plan of alerting carriers to the vulnerabilities associated with this procedure and calling for increased carriers' oversight. See appendix H for the full text of HCFA's comments.

ENDNOTES

1. At times oxygen dosages may range anywhere between 30 and 100 percent.

2. Camporesi, Enrico, Hyperbaric Oxygen Therapy: A Committee Report; Undersea and Hyperbaric Medical Society, Kensington, MD: Revised 1996.

3. The length of treatment is measured in total bottom time or TBT which does not include the time dedicated during ascent to increased atmospheric pressure or descent to surface pressure.

4. According to our review, 18 percent of beneficiaries exhibit side effects (significantly greater than the literature suggests). The most common side effect is ear-related trauma, representing 63 percent of all observed side effects. While side effects are generally not severe, two individuals within our sample showed signs of oxygen toxicity. This relates to 1.3 percent of the population which also is significantly greater than the expected value cited in the literature.

5. These statistics were based on our analysis of the 1998 National Claims History file maintained by HCFA. Estimated reimbursement for facility payments was based on an approximation of the proportion of payment attributed to HBO2 according to a cost to charge ratio calculated for revenue center 413 (hyperbaric oxygen treatment).

6. The Agency for Healthcare Research and Quality (AHRQ) was established in 1989 as the Agency for Health Care Policy and Research. "Reauthorizing legislation passed in November 1999 establishes AHRQ as the lead Federal agency on quality research. AHRQ, part of the U.S. Department of Health and Human Services, is the agency charged with supporting research designed to improve the quality of health care, reduce its cost, and broaden access to essential services. AHRQ's broad programs of research bring practical, science-based information to medical practitioners and to consumers and other health care purchasers.

   In December 1995, the Agency for Health Research and Quality (AHRQ) wrote a memo to HCFA regarding the medical conditions covered by the CIM 35-10 finding that "patterns of use do not validate the clinical effectiveness of any intervention, and it cannot be concluded that its use by proponents has either established its acceptance by the general medical community or provided acceptable proof of clinical utility."

7. In evaluation of the costs and benefits of using HBO2 to treat diabetic feet, the American Diabetic Association (ADA) recently concluded that, although adequate research (randomized controlled trials) was not available, HBO2 use "is reasonable" to treat severe and limb- or life-threatening wounds. (Special Report by the ADA, "Consensus Development Conference on Diabetic Foot Wound Care, 7-8 April 1999, Boston MA", Advances in Wound Care, Vol. 12: No. 7; September 1999.)

8. The Blue Cross and Blue Shield Association, Technical Assessment Center; Assessment Program Vol. 14: No. 13: August, 1999.

9. For simplicity in this figure, each beneficiary was counted in only one category based on a prioritization of conditions. Also note that some indications were combined to create a more meaningful breakdown of the indications.

10. Conditions not covered by the 35-10 guidelines including conditions not meeting the qualifications (e.g., chronic and refractory) were counted in the category 'non-covered indications'. The discrepancy between non-covered conditions as primary indications (33.5%) and treatments not compliant with CIM 35-10 (22.4%) describes courses of therapy that either (1) were compliant with CIM 35-10 based on a secondary or tertiary indication, or (2) were identified as being compliant by the physician reviewers, but a covered condition was not indicated as a reason for treatment.

11. Schwab, Robert (On Small Business), Denver Post; "Health care tempts firms local entrepreneurs market new products in growing field."; Denver, Colo.; Oct 17, 1998.

12. Commenting on Appendix D of this report, one representative of UHMS stated, *"This is the crux of this issue as far as HBO2 in the broad picture of wound healing is concerned. Both of the US professional organizations responsible for providing clinical guidelines, similar international organizations, and now BC/BS with its recent endorsement of HBO2 for chronic non-healing wounds (Assessment Program vol 14: No 13, Aug, 1999) define the clear value of HBO2 in ischemic/hypoxic wounds where such hypoxia cannot be adequately corrected by other means (refer also to the ADA statement (Diabetes Care 22(8): 1354-1360, 1999) but responsive to HBO2 should be treated. Reputable hyperbaric physicians around the country have tried to treat these patients on the basis of good experimental and clinical evidence justifying their treatment plan in terms of arterial insufficiency and acute ischemia as the only available means to describe the aforementioned hypoxic wound. HCFA has not kept pace with this long standing recommendation by the UHMS Oxygen Therapy Committee (dating back at least to 1989), the recent ADA recommendation, and now the recommendation by the BC/BS technology assessment. We have medically and physiologically defined these wounds using the best available descriptions of ischemia, but this is really both inadequate and confusing and should be resolved by a clearly defined new indication and terminology."*

13. One source of confusion in CIM 35-10 is the potential parallel between covered and uncovered conditions. Acute peripheral arterial insufficiency and preparation and preservation of a compromised skin graft (covered conditions), may be used to describe or treat conditions that are explicitly uncovered such as cutaneous, decubitus, and stasis ulcers; or skin burns. There is no terminology as to which standard has precedence.

14. A chi-square test for this relationship was significant at $p<.001$ using a Sudaan-weighted sample.

15. A chi-square test of significance found relationships between compliance with the CIM 35-10 guidelines and several billing diagnosis in the Sudaan-weighted sample. Both positive and negative relationships were found to be significant. Those mentioned in the text (pyoderma and chronic ulcer) were more likely to be out of compliance.

16. The 37 percent represents beneficiaries who did not meet the review expectations in one or more of the two quality of care variables. This group may overlap with the group of beneficiaries having excessive treatments.

17. The variables evaluated for a relationship with physician attendance and their associated p values from a Sudaan-weighted chi-square follow:

Variable Quality	p Value with Attendance	p Value with Supervision
1. Compliance with 35-10	<.001	<.001
2. Sufficient progress noted to justify continued treatment	<.001	<.001
3. Appropriate testing prior to treatment	.023	.020
4. Either quality of care variables (appropriate testing or sufficient progress to justify continuation)	<.001	<.001

18. As one of our reviewers explained, it is difficult to determine if a physician is truly in attendance. There may be documentation of attendance; combined with other evidence suggesting that they were not there. Some examples of this include (1) notes are written by the nurse but signed by the doctor, (2) doctors have written notes but they do not follow the chronological sequence of the nurse's notes, (3) documentation that the doctor was paged or faxed. Despite these difficulties, we asked our panel of experts to make a judgement regarding the level of attendance present.

19. There is some debate as to whether the requirement of 60 hours of hyperbaric education was intended to be a single course or should be divided between multiple courses.

20. The chi-square relationship is significant at p=.001

21. The CIM 35-10 designates that a medical review should be performed in instances that the course of therapy exceeds two months.

22. A relationship between appropriateness of the billed diagnosis and compliance with the CIM 35-10 guidelines was found to be a significant chi=square relationship at p=.001 in the Sudaan weighted sample.

23. Medical directors self-reported whether the following conditions would elicit a medical review:

1. Bills for indications not covered under 35-10	81%
2. Treatments courses extending beyond two months	31%
3. Any measure of length of treatment	43%
4. Conditions 1 and 2 (as listed above)	25%
5. Conditions 1 and 3 (as listed above)	41%

24. Medical directors self-reported their medical review process to include:

Confirm treatment is not over-utilized	53%
Confirm progress is monitored appropriately	65%
Confirm primary therapy for condition is also provided	65%

25. The currently effective version of the CIM 35-10 is separated into four distinct sections: A, B, C, and D. Part A identifies the conditions that are covered. Part B identifies explicit conditions that should not be covered. Part C states that reasonable utilization parameters should be used; and, Part D states that topical oxygen does not qualify for reimbursement. One source of confusion is the potential parallel between covered and uncovered conditions. Acute peripheral arterial insufficiency and preparation and preservation of a compromised skin graft, covered conditions, may be used to describe or treat conditions that are explicitly uncovered such as cutaneous, decubitus, and stasis ulcers; or skin burns. There is no terminology as to which standard has precedence. There is currently some discussion that any new policy will remove the Part B restrictions; however, this act alone will not resolve this problem. Subpart C provides a short description of reasonable utilization parameters only specifically referencing length of therapy course. However, legal advice sought by Dr. Kelly Hill of the ACHM in 1995 found that "the section [Part C of the CIM 35-10] must be interpreted to expand rather than limit *covered* services." The attorney explained that "clearly if a provision contains lists which are both inclusive and exclusive, the proper reading of it would be that those items excluded are explicit. Since the provision cannot itemize all possible items inclusive, that part of the provision is expandable. Such is the case with Section 35-10 because Subpart C provides a mechanism where additional items may be considered as included. Such an interpretation is proper since it gives meaning to all subparts of Section 35-10, not just one subpart." (Letter dated 3/8/95 from Attorney Kent Masterson Brown to Kelly Hill, M.D.)

26. Meleney's Ulcer was originally defined in 1926 as "a progressively expanding infection created by the synergism between aerophilic and anaerobic/microaerophilic bacteria", the ACHM Preferred Practice Protocols now equate the terms Meleney Ulcer and progressive necrotizing infection. This reference now states that the diagnostic criteria includes "a slowly (1 to 2 cm per day) progressive, superficial necrotizing environment, and microvascular thrombosis in a full thickness ulcer."

27. R. Marx created a specific hyperbaric oxygen therapy protocol for the prophylactic treatment of osteoradionecrosis of the jaw prior to dental procedures. The use of this therapy is considered to be a standard of care by many dentists and hyperbaric physicians.

28. Marx, R., Johnson, R., Kline, S. "Prevention of Osteoradionecrosis: A Randomized Prospective Clinical Trial of Hyperbaric Oxygen Versus Penicillin," *JADA*, Vol. 111, July 1985.

Marx, R. "A New Concept in the Treatment of Osteoradionecrosis," J Oral Maxillofacial Surgery 1983; 41: 283-288.

Marx,R., and Myers, R. "Use of Hyperbaric Oxygen in Postradiation Head and Neck Surgery," *NCI Monographs*, Number 9, 1990.

Epstein, J., Lepawsky, M., McKenzie, M., et al. "Hyperbaric Oxygen and Postradiation Osteonecrosis of the Mandible," *Oral Oncol, Eur J Cancer*, Vol 29B, No. 3, 201-207, 1993.

Consensus Statement: Oral Complications of Cancer Therapies. National Institutes of Health Consensus Development Panel. *NCI Monographs*, Number 9, 1990.

Bergstrom, K., Branemark, P., Granstrom, G., et al. "A Detailed Analysis of Titanium Implants Lost in Irradiated Tissue," *The International Journal of Oral & Maxillofacial Implants*, Vol 9, No 6, 1994.

Dempsey, J., Hynes, N., Smith, T., et al. "Cost Effectiveness Analysis of Hyperbaric Therapy is Osteoradionecrosis," *Can J Plast Surg.*, Vol 5, No 4, Winter 1997.

29. Less than 40 percent had both progress measures and a plan of care in any form.

30. ACHM "Physician Duties in Hyperbaric Medicine", 1993. Wound care is referenced under Physician Work Performed Before or After Hyperbaric Treatment, with the Patient numbers 3-5.

APPENDIX A

Cellular and Biochemical Benefits of Hyperbaric Oxygen

Although the number of indications for hyperbarics may be quite large, the mechanisms of therapy are few. HBO2 is believed to (1) enhance perfusion, (2) stimulate angiogenesis, (3) supersaturate the bloodstream with oxygen, (4) act as a bactericide, and (5) prevent the production of alpha toxin. The theories supporting these mechanisms are based on fundamental principles of medicine and physics.

Perfusion

Hyperbaric oxygen therapy increases the concentration of dissolved oxygen in the blood, which enhances perfusion. "At sea level the blood (plasma) oxygen concentration is .3 ml per deciliter of blood, assuming normal perfusion. 100% oxygen at ambient (normobaric pressure increases the amount of oxygen dissolved in the blood fivefold to 1.5 ml per deciliter, and at 3 atmospheres, the dissolved oxygen content is approximately 6 ml per deciliter, more than enough to meet resting cellular requirements without any contribution from oxygen bound to hemoglobin."[2]

Angiogenesis

Hyperbaric oxygen therapy stimulates the formation of a collagen matrix so that angiogenesis, a necessary component of wound healing, may take place.

Supersaturation of Blood with Oxygen

Hyperbaric oxygen therapy replaces inert gas in the bloodstream with oxygen, which is then metabolized by the body. "Boyle's law, which states that the volume of gas in an enclosed space is inversely proportional to the pressure exerted on it, governs this process and explains some of the beneficial effects of hyperbaric oxygen in conditions caused by the formation of gas bubbles."[2]

Bactericide

- Kills certain anaerobes
- Prevents growth of species such as Pseudomonas
- Restores neutrophil-mediated bacterial killing in previously hypoxic tissues

Hyperbaric oxygen therapy reduces leucocyte adhesion in reperfusion injury, preventing the release of protease and free radicals which cause vasoconstriction and cellular damage. "Local hypoxia predisposes wounds to infection, because the neutrophil-mediated killing of bacteria by free radicals is decreased. HBO restores this defense against infection and increases the rate of killing of some common bacteria by phagocytes. In addition, HBO alone is bactericidal for certain anaerobes."[2]

Prevention of the Production of Alpha Toxin

Hyperbaric oxygen therapy inhibits the production of alpha toxin, a by-product of gas gangrene.

Sources:

1. Leach, et al. , “ABC of oxygen: Hyperbaric oxygen therapy”; British Medical Journal; London: 1998.

2. Tibbles and Edelsberg, “Hyperbaric Oxygen Therapy”; The New England Journal of Medicine; Massachusetts Medical Society: 1996.

APPENDIX B

Section 35-10 of the Coverage Instruction Manual

[35-10 HYPERBARIC OXYGEN THERAPY

For purposes of coverage under Medicare, hyperbaric oxygen (HBO) therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure.

A. Covered Conditions.

Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one man unit) and is limited to the following conditions:

1. Acute carbon monoxide intoxication.

2. Decompression illness.

3. Gas embolism.

4. Gas gangrene.

5. Acute traumatic peripheral ischernia. HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened.

6. Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened.

7. Progressive necrotizing infections (necrotizing fasciitis, meleney ulcer).

8. Acute peripheral arterial insufficiency.

9. Preparation and preservation of compromised skin grafts.

10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management.

11. Osteoradionecrosis as an adjunct to conventional treatment.

The following uses of HBO are covered for services rendered on and after 10/1/82.

12. Soft tissue radionecrosis as an adjunct to conventional treatment.

13. Cyanide poisoning.

The following use of HBO is covered for services rendered on or after 2/22/84

14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment.

B. Noncovered Conditions

No program payment may be made for HBO in the treatment of the following conditions:

1. Cutaneous, decubitus, and stasis ulcers.

2. Chronic peripheral vascular insufficiency.

3. Anaerobic septicemia and infection other than clostridial.

4. Skin burns (thermal).

5. Senility.

6. Myocardial infarction.

7. Cardiogenic shock.

8. Sickle cell crisis.

9. Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary insufficiency.

10. Acute or chronic cerebral vascular insufficiency.

11. Hepatic necrosis.

12. Aerobic septicemia.

13. Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoffs disease).

14. Tetanus.

15. Systemic aerobic infection

16. Organ transplantation,

17. Organ storage.

18. Pulmonary emphysema,

19. Exceptional blood loss anemia

20. Multiple Sclerosis,

21. Arthritic Diseases.

Effective for services rendered on or after September 6, 1984:

22. Acute cerebral edema.

C. Reasonable Utilization Parameters

Make payment where HBO therapy is clinically practical. HBO therapy should not be a replacement for other standard successful therapeutic measures. Depending on the response of the individual patient and the severity of the original problem, treatment may range from less than 1 week to several months duration, the average being 2 to 4 weeks. Review and document the medical necessity for use of hyperbaric oxygen for more than 2 months, regardless of the condition of the patient, before further reimbursement is made.

D. Topical Application of Oxygen

This method of administering oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy has not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen. (Cross refer: §35-31.)

APPENDIX C

Discussion of covered indications by Florida BC/BS

1. **Acute carbon monoxide intoxication** induces hypoxic stress. The cardiac and central nervous systems are the most susceptible to injury from carbon monoxide. The administration of supplemental oxygen is essential treatment. Hyperbaric oxygen causes a higher rate of dissociation of carbon monoxide from hemoglobin than can occur breathing pure air at sea level pressure. The chamber compressions should be between 2.5 and 3.0 atm abs. It is not uncommon in patients with persistent neurological dysfunction to require subsequent treatments within six to eight hours, continuing once or twice daily until there is no further improvement in cognitive functioning.

2. **Decompression illness** arises from the formation of gas bubbles in tissue or blood in volumes sufficient enough to interfere with the function of an organ or to cause alteration in sensation. The cause of this enucleated gas is rapid decompression during ascent. The clinical manifestations range from skin eruptions to shock and death. The circulating gas emboli may be heard with a doppler device. Treatment of choice for decompression illness is HBO2 with mixed gases. The result is immediate reduction in the volume of bubbles. The treatment prescription is highly variable and case specific. The depths could range between 60 to 165 feet of sea water for durations of 1.5 to over 14 hours. The patient may or may not require repeat dives.

3. **Gas embolism** occurs when gases enter the venous or arterial vasculature embolizing in a large enough volume to compromise the function of an organ or body part. This occlusive process results in ischemia to the affected areas. Air embolism may occur as a result of surgical procedures (e.g., cardiovascular surgery, infra-aortic balloons, arthroplasties, or endoscopies), use of monitoring devices (e.g., Swan-Ganz introducer, infusion pumps), in nonsurgical patients (e.g., diving ruptured lung in respirator-dependent patient, infection of fluids into tissue space), or traumatic injuries (e.g., gunshot wound, penetrating chest injuries). Hyperbaric oxygen therapy is the treatment of choice. It is most effective when initiated early. Therapy is directed toward reducing the volume of gas bubbles and increasing the diffusion gradient of the embolized gas. Treatment modalities range from high pressure to low pressure mixed gas dives.

4. **Gas gangrene** is an infection caused by the clostridium bacillus, the most common being clostridium perfringens. Clostridial myositis and myonecrosis (gas gangrene) is an acute, rapidly growing invasive infection of the muscle. It is characterized by profound toxemia, extensive edema, massive death of tissue and variable degree of gas production. The most prevalent toxin is the alpha-toxin which in itself is hemolytic, tissue-necrotizing and lethal. The diagnosis of gas gangrene is based on clinical data supported by a positive [gram-stained] smear obtained from tissue fluids, X-ray radiographs, if obtained, can visualize tissue gas.

   The onset of gangrene can occur one to six hours after injury and presents with severe and sudden pain at the infected area. The skin overlying the wound progresses from shiny and tense, to dusky, then bronze in color. The infection can progress as rapidly as six inches per hour. Hemorrhagic vesicles may be noted. A thin, sweet-odored exudate

is present. Swelling and edema occur. The noncontractile muscles progress to dark red to black in color.

The acute problem in gas gangrene is to stop the rapidly advancing infection caused by alpha-toxin and to continue treatment until the advancement of the disease process has been arrested. The goal of HBO2 therapy is to stop alpha-toxin production thereby inhibiting further bacterial growth at which point the body can use its own host defense mechanisms. HBO2 treatment starts as soon as the clinical picture presents and is supported by a positive gram-stained smear. A treatment approach utilizing HBO2, is adjunct to antibiotic therapy and surgery. Initial surgery may be limited to opening the wound. Debridement of necrotic tissue can be performed between HBO2 treatments when clear demarcation between dead and viable tissue is evident. The usual treatment consists of oxygen administered at 3.0 atm abs pressure for 90 minutes three times in the first 24 hours. Over the next four to five days, treatment sessions twice a day are usual. The sooner HBO2 treatment is initiated, the better the outcome in terms of life, limb and tissue saving.

5. **Crush injuries and suturing of severed limbs, acute traumatic peripheral ischemia (ATPI), and acute peripheral arterial insufficiency**: Acute traumatic ischemia is the result of injury by external force or violence compromising circulation to an extremity. The extremity is then at risk for necrosis or amputation. Secondary complications are frequently seen: infection, non-healing wounds, and non-united fractures.

   The goal of HBO2 therapy is to enhance oxygen at the tissue level to support viability. When tissue oxygen tensions fall below 30 mmHg., the body's ability to respond to infection and wound repair is compromised. Using HBO2 at 2-2.4 atm, the tissue oxygen tension is raised to a level such that the body's responses can become functional again. The benefits of HBO2 for this indication are enhanced tissue oxygenation, edema reduction and increased oxygen delivery per unit of blood flow thereby reducing the complication rates for infection, nonunion and amputation.

   The usual treatment schedule is three 1.5 hour treatment periods daily for the first 48 hours. Additionally, two 1.5 hour treatment session daily for the next 48 hours may be required. On the fifth and sixth days of treatment, one 1.5 hour session would typically be utilized. At this point in treatment, outcomes of restored perfusion, edema reduction and either demarcation or recovery would be sufficient to guide discontinuing further treatments.

   For acute traumatic peripheral ischemic, crush injuries and suturing of severed limbs, Hyperbaric Oxygen Therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures, when loss of function, limb, or life is threatened. Arterial insufficiency ulcers may be treated by HBO2 therapy if they are persistent after reconstructive surgery has restored large vessel function.

6. The principal treatment for **progressive necrotizing infections (nectrotizing fasciitis, meleney ulcer)** is surgical debridement and systemic antibiotics. HBO2 is recommended as an adjunct only in those settings where mortality and morbidity are expected to be high despite aggressive standard treatment. One of the necrotizing infections, Meleney's ulcer, is a polymicrobial (mixed aerobic-anaerobic organisms) ulcer which slowly progresses affecting the total thickness of the skin. Also called a bacterial synergistic gangrene, the Meleney ulcer is associated with the formation of burrowing cutaneous fissures and sinus tracts that emerge at distant skin sites. This ulcer presents as a wide

area of pale red cellulitis that typically with a central area of granulation tissue encircled by gangrenous or necrotic tissue.

Another type of progression necrotizing infection is necrotizing fasciitis. This condition is a relatively rare infection. It is usually a result of a group A streptococcal infection beginning with severe or extensive cellulitis that spreads to involve the superficial and deep fascia, producing thrombosis of the subcutaneous vessels and gangrene of the underlying tissues. A cutaneous lesion usually serves as a portal of entry for the infection, but sometimes no such lesion is found.

7. **Preparation and preservation of compromised skin grafts** utilizes HBO2 for graft or flap salvage in cases where hypoxia or decreased perfusion have compromised viability. HBO2 enhances flap survival. Treatments are given at a pressure of 2.0 to 2.5 atm abs lasting from 90-120 minutes. It is not unusual to receive treatments twice a day. When the graft or flap appears stable, treatments are reduced to daily. Should a graft or flap fail, HBO2 may be used to prepare the already compromised recipient site for a new graft or flap. It does not apply to the initial preparation of the body site for a graft. HBO2 therapy is not necessary for normal, uncompromised skin grafts or flaps.

8. **Chronic refractory osteomyelitis** persists or recurs following appropriate interventions. These interventions include the use of antibiotics, aspiration of the abscess, immobilization of the affected extremity, and surgery. The Undersea and Hyperbaric Medical Society have defined "chronic" as existing six months or more. HBO2 is an adjunctive therapy used with the appropriate antibiotics. Antibiotics are chosen on the basis of bone culture and sensitivity studies. HBO2 can elevate the oxygen tensions found in infected bone to normal or above normal levels. This mechanism enhances healing and the body's antimicrobial defenses. It is believed that HBO2 augments the efficacy of certain antibiotics (gentamicin, tobramycin, and amikacin). Finally, the body's osteoclast function of removing necrotic bone is dependent on a proper oxygen tension environment. HBO2 provides this environment. HBO2 treatments are delivered at a pressure of 2.0 to 2.5 atm abs for a duration of 90-120 minutes. It is not unusual to receive daily treatments following major debridement surgery. The number of treatments required vary on an individual basis. Medicare Part B can cover the use of HBO2 for chronic refractory osteomyelitis that has been demonstrated to be unresponsive to conventional medical and surgical management.

9. HBO2's use in the treatment of **osteoradionecrosis and soft tissue radionecrosis** is one part of an overall plan of care. Also included in this plan of care are debridement or resection of non-viable tissues in conjunction with antibiotic therapy. Soft tissue flap reconstruction and bone grafting may also be indicated. HBO2 treatment can be indicated both preoperatively and postoperatively.

   The patients who suffer from soft tissue damage or bone necrosis present with disabling, progressive, painful tissue breakdown. They may present with wound dehiscence, infection, tissue loss and graft or flap loss. The goal of HBO2 treatment is to increase the oxygen tension in both hypoxic bone and tissue to stimulate growth in functioning capillaries, fibroblastic proliferation and collagen synthesis. The recommended daily treatments last 90-120 minutes at 2.0 to 2.5 atm abs. The duration of HBO2 therapy is highly individualized.

10. **Cyanide poisoning** carries a high risk of mortality. Victims of smoke inhalation frequently suffer from both carbon monoxide and cyanide poisoning. The traditional

antidote for cyanide poisoning is the infusion of sodium nitrite. This treatment can potentially impair the oxygen carrying capacity of hemoglobin. Using HBO2 as an adjunct therapy adds the benefit of increased plasma dissolved oxygen. HBO2's benefit for the pulmonary injury related to smoke inhalation remains experimental. The HBO2 treatment protocol is to administer oxygen at 2.5 to 3.0 atm abs for up to 120 minutes during the initial treatment.

Most patients with combination cyanide and carbon monoxide poisoning will receive only one treatment.

11. **Actinomycosis** is a bacterial infection caused by Actinomyces israelii. Its symptoms include slow growing granulomas that later breakdown, discharging viscid pus containing minute yellowish granules. The treatment includes prolonged administration of antibiotics (penicillin and tetracycline). Surgical incision and draining of accessible lesions is also helpful. Only after the disease process has shown refractory to antibiotics and surgery, should HBO2 be covered by Medicare Part B.

**Note that some of the 14 indications covered by CIM 35-10 are grouped into broader categories.

APPENDIX D

Appropriateness of Treatment

Appropriateness of Treatment ***(in % beneficiaries and total dollars)***

Class	%	SE (+/-)	ESTIMATED ALLOWED CHARGES (millions)	95% CONFIDENCE INTERVAL (millions)
INAPPROPRIATE	31.6	3.0	$14.2	$12.5 to $16.0
EXCESSIVE*	7.3	1.2	$4.9	$3.3 to $6.4
QUESTIONABLE QUALITY	20.2	2.55	$11.1	$9.7 to $12.6
APPROPRIATE	40.9	3.1	$19.7	$17.9 to $21.5
TOTAL	100	N/A	$49.9	N/A

**Dollars associated with excessive treatments include only the amount that was considered excessive, the remainder of the associated monies are included under the categories 'questionable quality' or 'appropriate'.*

Variables determining Appropriateness of Treatment
(in % beneficiaries and total dollars)

Class	N=378*			
	%	SE (+/-)	ESTIMATED ALLOWED CHARGES (millions)	95% CONFIDENCE INTERVAL (millions)
NO PROBLEM*	40.9	3.1	$18.8	$17.2 to $20.5
NO HBO2*	9.2	2.0	$3.7	$2.6 to $4.8
NOT CONSISTENT WITH 35-10*	22.4	2.6	$10.5	$9.1 to $11.9
EXCESSIVE TREATMENT*	12.9	1.7	$3.3	$2.2 to $4.3
TREATMENT BEYOND PLATEAU*	10.9	1.6	$2.7	$1.8 to $3.7
INADEQUATE TESTING*	20.0	2.5	$10.5	$9.3 to $11.8
INSUFFICIENT JUSTIFICATION OF CONTINUATION*	38.0	3.0	$19.6	$17.9 to $21.3

**Categories are not necessarily mutually exclusive. The proportion and dollars represent all beneficiaries whereas the first table above is prioritized (mutually exclusive) such that if a beneficiary's treatment was inappropriate, it was not included when considering excessive treatments or excessive quality care.*

APPENDIX E

Accepted Usage of HBO2 by HCFA and Interest Groups

Condition	HCFA	UHMS	ACHM	International
Bubbles				
Decompression Illness	Yes	Yes	Yes	Yes
Gas Embolism	Yes	Yes	Yes	Yes
Poisoning				
Acute Carbon Monoxide Intoxication	Yes	Yes	Yes	Yes
Cyanide Poisoning	Yes	Yes	Yes	Yes
Hydrogen Sulfide Poisoning	No	No	No	Yes
Carbon Tetrachloride Poisoning	No	No	No	Yes
Infections				
Clostridial Myonecrosis (Gas Gangrene)	Yes	Yes	Yes	Yes
Progressive Necrotizing Infection	Yes	Yes	Yes	Yes
Chronic Refractory Osteomyelitis	Yes	Yes	Yes	Yes
Meleney's Ulcer	Yes	Yes	Yes	Yes
Actinomycosis	**Yes**	**No**	**Yes**	**Yes**
Refractory Mycoses	No	No	No	Yes
Leprosy	No	No	No	Yes
Plastics				
Problem Wounds	**No**	**Yes**	**Yes**	**Yes**
Acute Peripheral Arterial Insufficiency	**Yes**	**No**	**Yes**	**Yes**
Compromised Skin Grafts	Yes	Yes	Yes	Yes
Thermal Burns	**No**	**Yes**	**Yes**	**Yes**
Aid to Re-Implantation Surgery	**No**	**Yes**	**No**	**Yes**
Traumatology				
Acute Traumatic Peripheral Ischemia	Yes	Yes	Yes	Yes
Crush Injury and Suturing of Severed Limbs	Yes	Yes	Yes	Yes
Compartment Syndrome	Yes	Yes	Yes	Yes
Soft tissue Sports Injuries	No	No	No	Yes

Condition	HCFA	UHMS	ACHM	International
Orthopedics				
Osteoradionecrosis	Yes	Yes	Yes	Yes
Soft-tissue Radionecrosis	Yes	Yes	Yes	Yes
Nonunion of Fractures	No	No	No	Yes
Bone Grafts	No	No	No	Yes
PVD-1				
Diabetic Wounds	**No**	**Yes**	**Yes**	**Yes**
Ischemic Gangrene (Related)	**No**	**Yes**	**Yes**	**Yes**
Leg Pain	No	No	No	Yes
PVD - 2				
Shock	No	No	No	Yes
Myocardial Ischemia	No	No	No	Yes
Aid to Cardiac Surgery	No	No	No	Yes
Neurological				
Stroke	No	No	No	Yes
Multiple Sclerosis	No	No	No	Yes
Migraine	No	No	No	Yes
Cerebral Edema	No	No	No	Yes
Multi-infract Dementia	No	No	No	Yes
Spinal Cord Injury	No	No	No	Yes
Vascular Diseases of the Spinal Cord	No	No	No	Yes
Intra cranial Abscess	No	Yes	No	Yes
Peripheral Neuropathy	No	No	No	Yes
Radiation Myelitis	No	No	No	Yes
Vegetative Coma	No	No	No	Yes
Hematology				
Sickle Cell Crises	No	No	No	Yes
Severe Blood Loss Anemia	No	Yes	No	Yes

Condition	HCFA	UHMS	ACHM	International
Opthamology				
Occlusion of Central Artery of Retina	No	No	No	Yes
Gastro-intestinal				
Gastric Ulcer	No	No	No	Yes
Necrotizing Enterocolitis	No	No	No	Yes
Paralytic Ileus	No	No	No	Yes
Pneumotiodes Cystoides Intestinalis	No	No	No	Yes
Hepatitis	No	No	No	Yes
Enhancement of Radiosensitivity of Malignant Ulcers				
Enhancement of Radiosensitivity	No	No	No	Yes
Otorhinolaryngology				
Sudden Deafness	No	No	No	Yes
Acute Acoustic Trauma	No	No	No	Yes
Labyrithitis	No	No	No	Yes
Meniere's Disease	No	No	No	Yes
Malignant Otitis Externa	No	No	No	Yes
Lung Disease				
Lung Abscess	No	No	No	Yes
Pulmonary Embolism	No	No	No	Yes
Endocrines				
Diabetes	No	No	No	Yes
Obstetrics				
Complicated Pregnancy - Diabetes	No	No	No	Yes
Congenital Heart Disease of the Neonate	No	No	No	Yes
Heart Disease	No	No	No	Yes
Placental Hypoxia	No	No	No	Yes
Fetal Hypoxia	No	No	No	Yes
Asphyxiation				
Drowning	No	No	No	Yes
Near Hanging	No	No	No	Yes
Smoke Inhalation	No	No	No	Yes

Condition	HCFA	UHMS	ACHM	International
Aid to Rehabilitation				
Spastic Hemiplegia of Stroke	No	No	No	Yes
Paraplegia	No	No	No	Yes
Chronic Myocardial Insufficiency	No	No	No	Yes
Peripheral Vascular Disease	No	No	No	Yes

APPENDIX F

Comparison of ICD-9 Interpretations *(HCFA vs. several LMRPs)*

Category	ICD-9	HCFA Proposal	TEXAS BC/BS*	FLORIDA BC/BS	Transamerica Southern CA	AR (LA) BC/BS
Date		**7/97**	**10/97**	**4/98**	**3/97**	**1/99**
Carbon Monoxide Poison	**986**	YES	YES	YES	YES	YES
Decompression Sickness	**993.3**	YES	YES	YES	YES	YES
Arterial Gas Embolism	**993.9**	NO	NO	YES	NO	YES
	958.0	YES	YES	YES	YES	YES
	999.1	NO	NO	NO	NO	YES
	996.7-996.79	NO	NO	NO	NO	YES
Gas Gangrene	**040.0**	YES	YES	YES	YES	YES
Crush Injuries and Severed Limbs	**906.4**	NO	NO	NO	YES	NO
	925.0	NO	NO	NO	NO	YES
	925.1-925.9	YES	NO	NO	NO	YES
	926	NO	NO	NO	NO	YES
	927.00-927.03	NO	YES	YES	YES	YES
	927.04-927.08	NO	NO	YES	YES	YES
	927.09-927.11	YES	YES	YES	YES	YES
	927.12-927.19	NO	NO	NO	YES	YES
	927.20-927.21	YES	YES	YES	YES	YES
	927.22-927.79	NO	NO	NO	YES	YES
	927.8-927.9	YES	YES	YES	YES	YES
	928.00-928.01	YES	YES	YES	YES	YES
	928.02-928.09	NO	NO	NO	YES	YES
	928.10-928.11	YES	YES	YES	YES	YES
	928.12-928.19	NO	NO	NO	YES	YES
	928.2-928.21	YES	YES	YES	YES	YES
	928.22-928.29	NO	NO	NO	YES	YES
	928.3	YES	YES	NO	YES	YES
	928.4-928.7	NO	NO	NO	YES	YES
	928.8-928.9	YES	YES	YES	YES	YES
	929.0	YES	YES	NO	NO	YES
	929.1-929.8	NO	NO	NO	NO	YES
	929.9	YES	YES	NO	NO	YES
	996.90-996.99	NO	NO	YES	NO	YES
Progressive Necrotizing Infections	**686.0**	NO	YES	NO	YES	NO
	686.01	YES	NO	YES	NO	NO
	686.09	YES	NO	YES	NO	YES
	728.86	YES	YES	YES	NO	YES
	785.4	YES	YES	NO	NO	NO

Category	ICD-9	HCFA Proposal	TEXAS BC/BS*	FLORIDA BC/BS	Transamerica Southern CA	AR (LA) BC/BS
Acute Traumatic Peripheral Ischemia	**900-902.52**	NO	NO	NO	NO	YES
	902.53	YES	NO	NO	NO	YES
	903.01	YES	NO	YES	NO	YES
	903.2	YES	NO	NO	NO	YES
	904.0	YES	NO	YES	NO	YES
	904.01-904.4	NO	NO	NO	NO	YES
	904.41	YES	NO	YES	NO	YES
	904.42-904.9	NO	NO	NO	NO	YES
	443.9	YES	YES	NO	YES	NO
	925-929	PARTIAL	PARTIAL	PARTIAL	PARTIAL	YES
	991.1	NO	NO	NO	YES	NO
	991.2	NO	NO	NO	YES	NO
Arterial Insufficiency	**250.7**	NO	NO	NO	NO	YES
	362.30-362.31	NO	NO	NO	NO	YES
	443.81	NO	NO	NO	NO	YES
	443.9	NO	NO	NO	YES	YES
	444.0-444.20	NO	NO	NO	NO	YES
	444.21	YES	YES	YES	NO	YES
	444.22	YES	YES	YES	NO	YES
	444.23-444.80	NO	NO	NO	NO	YES
	444.81	YES	YES	NO	NO	YES
	444.82-444.99	NO	NO	NO	NO	YES
	733.41-733.49	NO	NO	YES	NO	NO
Compromised Skin Grafts	**996.52**	YES	YES	YES	YES	YES
	996.90-996.96	YES	NO	NO	NO	NO
Osteomyelitis	**730.10-730.19**	YES	YES	YES	YES	YES
ORN	**526.89**	YES	YES	YES	YES	YES
	909.2	NO	YES	YES	YES	NO
	990	YES	YES	YES	YES	YES
STRN	**990**	YES	YES	YES	YES	YES
	909.2	NO	YES	YES	YES	NO
Cyanide	**987.7**	YES	NO	YES	NO	YES
	989.0	YES	NO	YES	YES	YES
Actinomycosis	**039.0-039.4**	YES	YES	YES	YES	YES
	039.5-039.7	NO	NO	YES	YES	YES
	039.8	YES	YES	YES	YES	YES
	039.9	YES	YES	YES	YES	YES

* Texas Blue Cross/Blue Shield is now Trailblazers.

APPENDIX G

Key Questions From the Medical Review Protocol

	N	%	S.E.	95% Confidence Interval
1. The ICD-9 codes billed to Medicare:				
A. Accurately Describe the Primary Indication	142	42.9	3.3	36.4 to 49.3
B. Approximate the Primary Indication	80	21.7	2.6	16.6 to 26.8
C. Describe a Secondary or Tertiary Indication	51	18.2	2.7	13.0 to 23.4
D. Seem Erroneous	47	13.1	2.2	8.8 to 17.5
E. Other	13	4.1	1.3	1.6 to 6.7
Total	**333**			
2. Did the physician establish a plan of care?				
A. Yes	154	45.6	3.2	39.2 to 52.0
B. Yes, but inadequate	65	17.7	2.4	12.9 to 22.4
C. Not documented	121	36.7	3.2.	30.5 to 43.0
Total	**340**			
3. Did the physician establish objective progress measures?		32.0	3.0	26.1 to 37.9
A. Yes	109	12.9	2.1	8.7 to 17.1
B. Yes, but inadequate	49	55.1	3.2	48.8 to 61.5
C. Not documented	181			
Total	**339**			
4. Was sufficient progress to justify continuation noted in the medical record?				
A. Yes	177	55.2	3.3	48.6 to 61.7
B. No	146	44.8	3.3	38.3 to 51.4
Total	**323**			
5. In your opinion, did treatments continue after benefits plateaued?				
A. Yes	73	13.2	1.8	9.6 to 16.8
B. No	191	63.2	3.1	57.2 to 69.2
C. Unable to determine	75	23.6	2.8	18.1 to 29.1
Total	**339**			
6. Was physician attendance specifically documented in the chart?				
A. Always	101	27.5	2.9	21.9 to 33.1
B. Sometimes	66	20.6	2.7	15.3 to 25.9
C. Never	171	51.7	3.3	45.3 to 58.1
Total	**338**			

7. Does it appear that a physician was present?				
A. Yes	145	39.0	3.1	32.8 to 45.1
B. No	135	44.1	3.3	37.8 to 50.5
C. Unable to determine	55	16.2	2.4	11.4 to 20.9
Total	**335**			
8. Is there evidence that the physician was supervising treatments?				
A. Yes	207	58.8	3.3	52.4 to 65.2
B. No	75	25.2	2.9	19.4 to 30.9
C. Unable to determine	52	16.1	2.5	11.2 to 20.9
Total	**334**			
9. Did the patient receive appropriate testing for the diagnosis?				
A. Yes	223	67.2	3.1	61.2 to 73.2
B. No	83	22.0	2.7	16.8 to 27.3
C. Unable to determine	33	10.8	2.1	6.7 to 14.8
Total	**339**			
10. Was treatment prior to initial HBO2 appropriate?				
A. Yes	212	63.0	3.2	56.8 to 69.2
B. No	38	10.7	2.1	6.7 to 14.8
C. Unable to determine	88	26.3	2.9	20.6 to 32.0
Total	**338**			
11. Was payment and coverage consistent with HCFA's 35-10 guidelines?				
A. Yes	239	72.9	2.9	67.1 to 78.6
B. No	84	25.6	2.9	19.9 to 31.3
C. Unable to determine	8	1.6	0.6	0.4 to 2.7
Total	**331**			

Agency Comments

In this appendix, we present comments from the Health Care Financing Administration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

SEP 22 2000

DATE:

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle
Administrator

SUBJECT: Office of the Inspector General (OIG) Draft Report: "Hyperbaric Oxygen Therapy: Its Use and Appropriateness," (OEI-06-99-00090)

We appreciate the opportunity to comment on the above-referenced report. The Health Care Financing Administration (HCFA) appreciates your interest in hyperbaric oxygen therapy (HBO). Our goal is to make sure Medicare beneficiaries have access to the most effective, safe medical treatments, while paying appropriately for these services.

HBO is a treatment in which the patient is placed in a compression chamber with high concentrations of oxygen at multiple atmospheric pressures. It is used for a variety of conditions; Medicare currently covers 14 conditions (e.g., carbon monoxide intoxication and crush injuries). Medicare spends approximately $76 million annually on HBO therapy.

We have been concerned for some time about Medicare coverage policy regarding HBO. This is why we began an effort in 1999 to clarify existing policies. In April 1999, we issued a revision to the Medicare Coverage Issues Manual that would have implemented several of your report's recommendations. We remain committed to making these program improvements. However, HCFA has delayed implementation of the revised coverage policy. This delay is in the best interest in the Medicare program and its beneficiaries because further study and analysis is needed of this issue. I also believe that HCFA needed to respond to the medical community's characterizations that the manual revision could have reduced coverage and imposed new requirements such as physician attendance during an HBO session. As part of this process, HCFA staff are continuing to discuss these matters with hospital representatives, who often own the pressure chambers, and physicians who administer and supervise the treatment.

We appreciate all of the work the OIG has done in researching and preparing their draft findings and recommendations on this important subject. We believe the report will be helpful to us in clarifying our polices for Medicare coverage of HBO. Our specific comments to the report's recommendations are below.

OIG Recommendation
HCFA should initiate a national coverage decision process for HBO2.

HCFA Response
We concur that HCFA should render a national coverage decision to address confusion and inconsistency surrounding local coverage policies of HBO. This month HCFA received a formal request for consideration of physician attendance in an HBO setting. We also shortly expect another formal request to address the treatment for compromised skin grafts and chronic non-healing wounds. As a result, HCFA will initiate the national coverage decision process. We will thoroughly review the relevant medical literature and scientific evidence as we develop a national coverage decision.

OIG Recommendation
HCFA should improve policy guidance.

1. ***Provide clear descriptions of covered conditions;***
   We agree that there is a need for clear descriptions of certain covered conditions (e.g., the extent of coverage of skin grafts). Clear descriptions of covered conditions serve to improve compliance with coverage policy. To this end, HCFA issued a program memo that restated the current HBO coverage policy in March 2000. For example, the program memo included a clarification describing the criteria that must be met in order to satisfy the definition of a compromised skin graft that would be eligible for reimbursement. This issue is raised in the OIG report and is of interest to HCFA's claims processing contractors and to providers.

2. ***Propose additional ICD-9 codes as needed to more closely parallel covered conditions;***
   We concur. As HCFA works to clarify and further define covered conditions, we will examine the need to add additional ICD-9 codes.

3. ***Establish a clear physician attendance policy;***
   In our discussions on physician supervision requirements, we have noted differences of opinion among provider groups regarding the risk levels associated with HBO. Some organizations such as the American College of Surgeons, have expressed the view that having a physician in the immediate vicinity would be sufficient to ensure patient safety, while others, recommend that a physician be physically present in the room during an HBO session. Our customary policy is to defer to state licensing and certification when issues of qualifications arise. We received a formal request in September 2000 for a national coverage decision on physician attendance. We will review the scientific evidence and medical literature pertinent to this request as we make a national coverage decision.

4. ***Consider establishing training requirements,***
   HCFA will consider including the issue of training requirements in the policy. We recognize that varying local policies have been a source of confusion. However, professional associations such as the AMA and the AHA have related to HCFA concerns of interference with local authority on such issues. As noted on page 13 of the

draft OIG report, the HBO medical societies and the AMA have expressed the view that credentialling is the responsibility of the hospitals or licensing boards, and does not meaningfully fall under the jurisdiction of the Federal government.

5. ***Consider incorporating clinical standards of patient selection and treatment protocols designed with the aid of hyperbaric physicians; and***
We concur with the need for clinical standards of patient selection and treatment protocols. Therefore, HCFA will carefully review and consider the existing guidelines designed by hyperbaric physicians for professional associations.

6. ***Specify medical record documentation requirements.***
We agree that the medical record should clearly and fully support the need for HBO services. When Medicare's claims processing contractors identify insufficient documentation to support medically reasonable and necessary services, they are instructed to provide feedback and education to the provider.

OIG Recommendation
HCFA should improve oversight.

1. Require contractors to initiate edits and medical review procedures, which ensure that uncovered diagnoses are not paid, and high treatment thresholds are subject to review.

2. Explore the establishment of a registry of facilities and/or physicians providing HBO to improve communication and facilitate monitoring.

HCFA Response

We agree that carriers should have system edits in place for the autodenial of claims submitted for physician supervision of HBO treatments (CPT code 99183) when the diagnosis listed on the claim is not a covered diagnosis. During our next scheduled conference with carriers, we will share the recommendations of this report. We will ask the carriers to conduct periodic data analysis on CPT code 99183 with particular focus on those claims submitted for HBO which has been ongoing for more than two months. According to the results of the analysis, the carrier will follow HCFA's progressive corrective action instructions that may range from provider education to complex medical review with associated overpayment collection, and/or referral to the Benefit Integrity Unit. In addition, we will advise carriers of the vulnerability to Medicare of the over-utilization of HBO therapy both in our routine calls with carriers and in our periodic vulnerability reports, which are issued to all contractors. We will ask carriers to analyze their data and target review on potentially excessive HBO therapy and to take necessary action to correct billing for this service.

A registry of facilities or physicians providing HBO could be useful to improve communication and facilitate monitoring . HCFA will explore the establishment of such a registry, however, we note that the we must evaluate the potential benefits of a registry in light of available resources.